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CHROMAVISION MEDICAL SYSTEMS, INC.
ANNUAL REPORT

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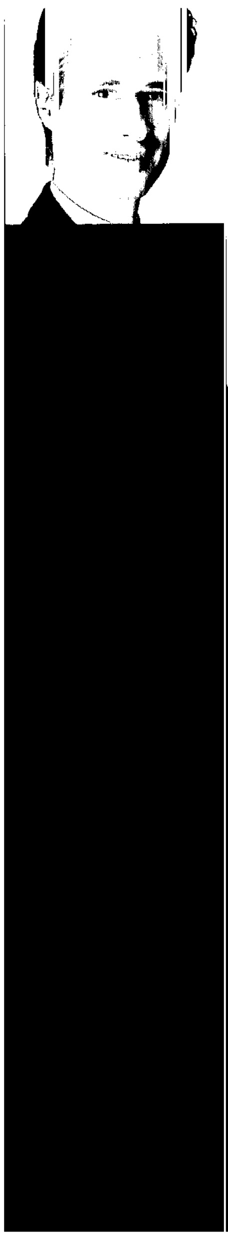
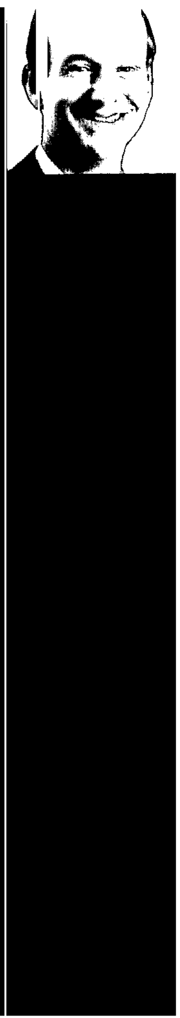




A MESSAGE TO OUR SHAREHOLDERS

ChromaVision's beginnings are rooted in vision. In 2001, seeing our vision become a reality spurred our teams to surpass milestones, cultivate new and innovative strategies, and propel ChromaVision to become the leader in our field. It was truly a challenging and remarkable year.

The ACIS® digital microscope system is now a proven product in clinical use throughout the United States and a growing number of countries worldwide. The demonstrated market acceptance of the ACIS has grown rapidly in tandem with a documented, recurring revenue stream.

Many of our clients have moved past acceptance to advocacy, promoting the benefits of ACIS within their networks and expressing their desire to perform additional applications using the ACIS technology. Working directly with our clients to "FastTrak" these new applications has proven the success of ACIS as a broad technology platform.

We believe that every area of our business is demonstrating tangible proof that our vision is on target—sales and revenue momentum, reimbursement, customer service, and quality. The foundation we have built in each of these areas has positioned us to achieve both our near- and long-term milestones. And, as evidenced by the metrics that track our progress, commercial trends continue to build, putting us well on our way to achieving the aggressive deliverables that we have defined as our goals. 2002 will clearly be an extraordinary year.

To provide a unique, flexible technology platform to revolutionize ...nic pathology ...ng

b e c o m e s

Customers are driving the introduction of new ACIS applications, having moved beyond early adoption to advocacy

R E A L I T Y

A VISION SHARED

Although 2001 was a remarkable year, it does not come as a surprise. It is a logical continuation of the consistently positive results that have become our foundation. Our sales momentum continues to build as our vision becomes a vision shared. In fact, the near 50% average growth in recurring revenue we garnered each quarter in 2001 mirrored the growth rates of the previous four quarters.

Since our inception, our vision has been focused on assisting physicians in accurately assessing cell-based disease. Central to achieving this goal has been our ACIS, which combines automated microscopy and computerized image analysis to detect, count, and classify cells of clinical interest based on color, size and shape. These capabilities enable the system to assist pathologists by providing accuracy, precision, and reproducibility for slide-based analysis—critical advantages in medical decision making.

Our commercial success has validated our vision. Respected clinical and national laboratories, such as US LABS, Inc., AmeriPath, Inc., Kaiser Permanente, Stanford University, and others have led the way in embracing the ACIS platform. Endorsement in the research and biopharma fields has also been demonstrated by a growing list of clients and collaborators, including Abbott Laboratories, ImClone Systems, SUGEN and Cell Pathways.

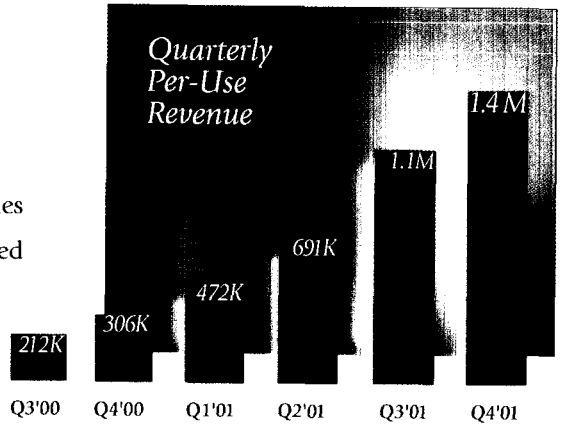
DELIVERING THROUGH INNOVATIVE STRATEGIES

Anticipating both obstacles and opportunities has led us to create proactive strategies that have opened doors and fueled our drive forward. For example, we've approached third-party payers and medical directors with information illustrating how physicians are using the ACIS system as a tool in their laboratory testing. These proactive efforts have been successful. Every carrier that has rigorously scrutinized ACIS-assisted testing has concluded that its use is appropriate, medically necessary, and brings quantifiable economic value to the healthcare system.

Our strong reimbursement position, prestigious placements, and per-use-billing program, have removed barriers to sales, resulting in over 140 total customers and 45,000

50%

Approximate average rate of growth in per-use revenue, realized quarter over quarter in 2001



Excludes system sales and other revenue

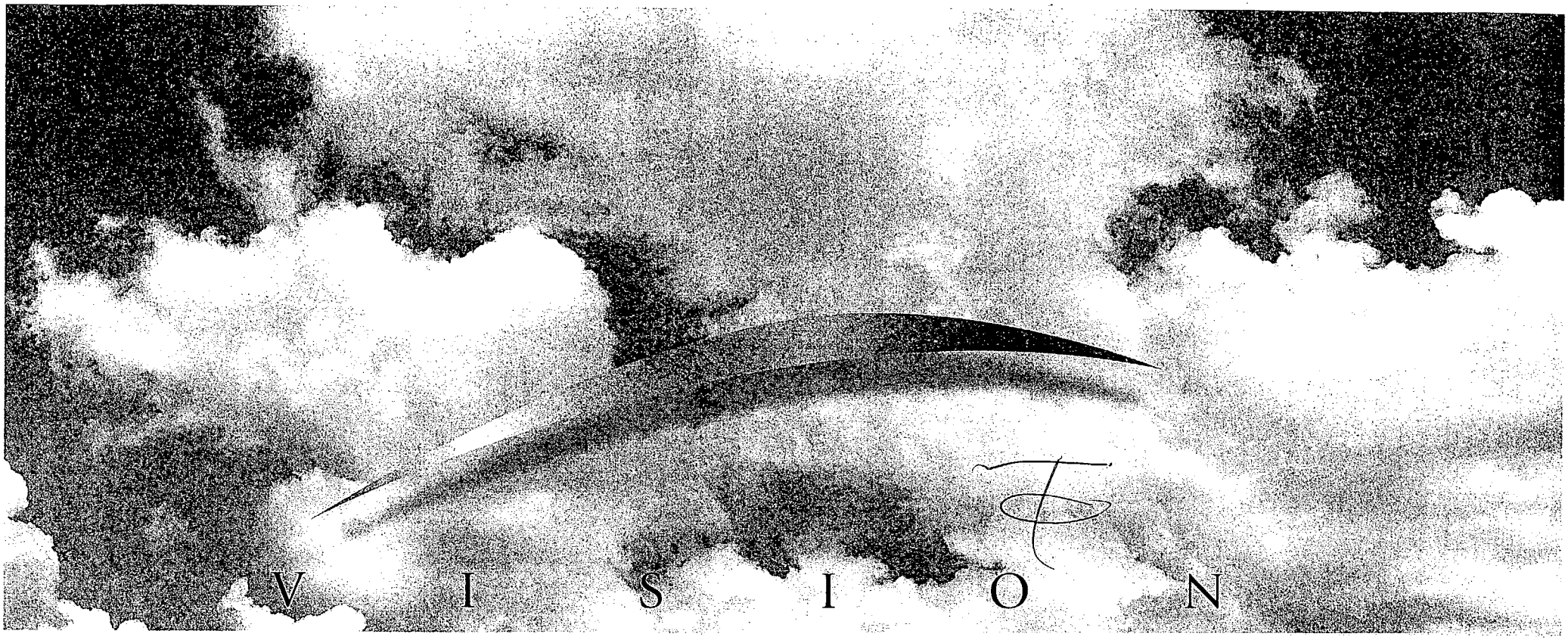
VISION

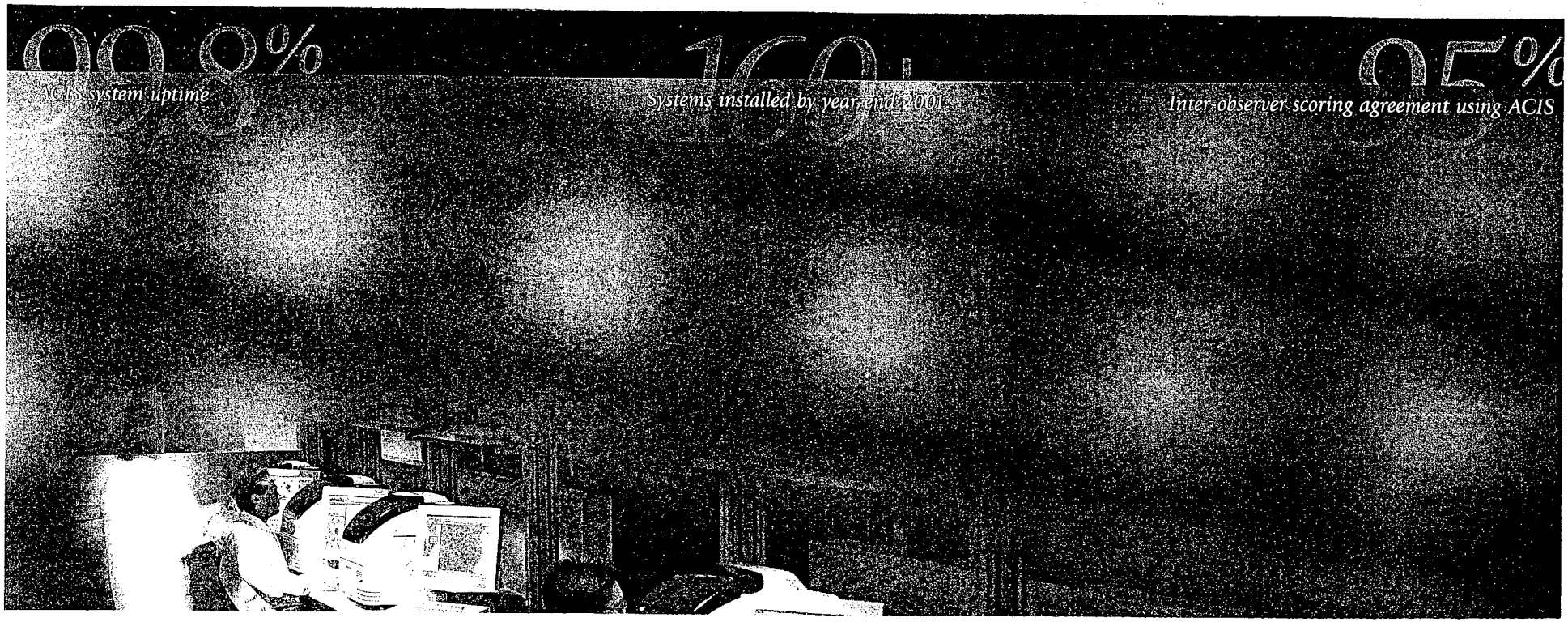
In order to reach a broader base of potential customers, ACIS use must also be practical in small, [illegible]spitals and [illegible]atories

becomes

Our remote pathology initiative availed the ACIS revolutionary technology to more than 40 of these customers in 2001

REALITY


VISION


99.9%
ACIS system uptime
160+
Systems installed by year-end 2001
95%
Inter-observer scoring agreement using ACIS

billable tests performed by year end. Mid-year we recognized that the demand for our technology had grown beyond the higher volume reference laboratories to smaller hospitals and labs throughout the country. We answered this demand, announcing our remote pathology initiative in a pilot program with Irvine, California-based US LABS, Inc. By year-end, through co-marketing with US LABS, contracts for 41 ACIS remote workstations had been signed. Our partnership with US LABS represents a major annual market opportunity with additional growth potential.

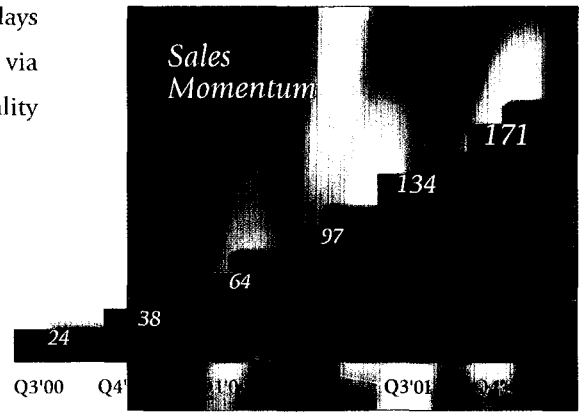
As our installed user base grows, we recognize that the quality of our product and service increases in importance. Our efforts this past year yielded impressive results. Two new software releases optimized the user interface and system performance, while contributing to an overall reduction in system cost, an uptime of 99.8% and over 240 days between unscheduled service calls. Our ability to access and operate clients' systems via modem makes rapid service possible and economical. Innovation makes our reality one to be proud of.

45,000

Number of tests using ACIS, billed and reimbursed by year-end 2001

DEFINING SUCCESS

The proactive implementation of innovative strategies has laid the groundwork for a year of unprecedented success in 2002. Expanding the menu of applications on the ACIS system is key to the realization of our goals. As our broad FDA clearance covers our platform imaging technology, there is not a need to seek clearance for each new application that our customers wish to perform using the system. Potential competitors and competing technologies would likely be subject to individual application clearances.



Rapid growth in customer acceptance resulted in 171 total executed contracts at year end 2001

99.8%

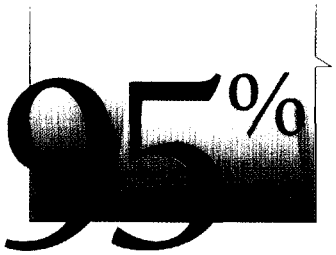
ACIS system uptime

As a result, we've begun working closely with our customers to support them in identifying additional markers utilizing the existing capabilities of the ACIS system. Our customers have initially identified and are currently in the process of validating 17 of these new markers. This cooperation with our customers may result in the rapid introduction of new applications on the ACIS—all with what we anticipate to be little impact on our internal R&D operations and costs.

HELPING TO SPEED DRUG DELIVERY

Our growing focus on the biopharmaceutical market has yielded important results: we've gained high profile customers, collaborators and significant market interest. Our partners and clients have recognized the ACIS advantages of precise quantitation, reproducibility, and perhaps most importantly in the frenetically paced world of drug development, speed and automation. ACIS provides a clear advantage for drug companies anxious to get to market with the 400 new cancer drugs currently in late stage clinical trials and another 1,400 in pre-clinical and early clinical studies. ChromaVision and the ACIS are uniquely positioned to service this market, thanks to our technology.

The ACIS brings previously unavailable capabilities ideally suited to researchers—such as automated tissue microarray imaging, facilitating the analysis of literally thousands of specimens in a single experiment. Research users have acknowledged their ability to generate invaluable information unobtainable through other methods of analysis. Developing relationships with biopharma partners is a high priority for ChromaVision, evidenced by our recent addition of a dedicated biopharma representative and support team. We are also expanding our marketing program in this area as part of our aggressive efforts to capture a significant share of this market.



Our multi-pathologist study data published in 2001 showed that inter-observer scoring agreement improved from 72% with manual testing to 95% using ACIS

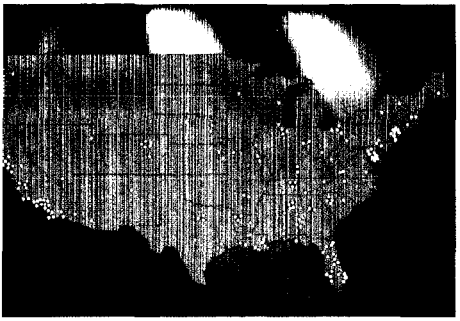
EXPANDED PRODUCT OFFERINGS AND NEW MARKETS

Increasing the number of system installations and the volume on each system is our primary focus for 2002. We anticipate that over 250 ACIS systems and remote workstations will be up and running by the close of 2002. Individual account volumes are also projected to continue upward, contributing to a significant growth in revenue over 2001. We feel confident in these statements, because our trends lead soundly in this direction. But we also see new strategies as having a significant role in this growth—exciting new strategies that are already taking shape.

The ACIS system was designed to provide measurable, consistent and standardized results. Due to the system's sensitivity, the quality of the stains and the staining process used in slide preparation are key to providing an accurate result. For the most part,

stains and reagent kits currently available on the market have been developed for manual interpretation—not image analysis. We have addressed this opportunity by developing our own line of reagents that have been optimized for image analysis. We expect that the first of these reagents will be available to our customers in the first half of 2002. While improving quality control, these consumables will also generate additional revenue.

To further improve our ability to achieve standardization, we also plan to offer a ChromaVision branded automated staining device. Like the reagents, it will be optimized for use with the ACIS. Together, these complementary products will streamline clients' operations and improve workflow, offering a single point of data entry. The initiation of this new strategy resulted primarily through customer feedback and demand.



In 2001 use of the ChromaVision technology expanded presence to 36 of the 50 US States

A NEW REALITY

All levels of our organization—including senior management—are also focused on establishing relationships with large national reference laboratories. Our aggressive targeting of high volume customers is just part of the effort that will move us closer to perhaps our most significant milestone to date. If successful, we will have reached the break-even point at a comparatively early point in our history. Such a milestone has energized us all and will drive our momentum toward profitability in 2003 and beyond—creating an entirely new reality and new value for all of us at ChromaVision and for our stockholders.

160+

Systems installed by year end 2001

BOARD OF DIRECTORS

DOUGLAS S. HARRINGTON, M.D.
Chairman of the Board
ChromaVision Medical Systems, Inc.

President and
Chief Executive Officer, Retired
PacifiCare of California
Vice President, Western Region, Retired
PacifiCare Health Systems, Inc.,
a leading managed health care
services company

MARY LAKE POLAN, M.D., PH.D.
Professor and Chairman, Department
of Gynecology and Obstetrics
Stanford University School of
Medicine, an educational institution

Vice President, Operations
and Management Services
Safeguard Scientifics, Inc., a developer
and operator of premiere technology
companies with a focus on software,
communications and eServices

CARL W. APPLEFACE
Chief Executive Officer
and President
ChromaVision Medical Systems, Inc.

Business Consultant
Managing Partner, Retired
Ernst & Young LLP, a leading profes-
sional services organization and
accounting firm

CHARLES A. ROOT
Executive Vice President,
Corporate Director, Retired
Safeguard Scientifics, Inc., a developer
and operator of premiere technology
companies with a focus on software,
communications and eServices

Business Consultant
Former Senior Vice President,
General Counsel and Corporate
Secretary of MiniMed Inc.,
a company providing therapies
for the treatment of diabetes

[illegible]

[illegible]
Chief Executive Officer and
President

[illegible]
Vice President,
Chief Science Officer

[illegible]
Chief Operations Officer,
Chief Financial Officer

[illegible]
Vice President,
Operations

[illegible]
Vice President,
Chief Technology Officer

[illegible]
Vice President,
Marketing

INDEPENDENT AUDITORS

KPMG LLP
600 Anton Boulevard, Suite 700
Costa Mesa, CA 92626
(714) 850-4300
(714) 850-4488 Fax
www.kpmg.com

LEGAL COUNSEL

Gibson, Dunn & Crutcher LLP
333 South Grand Avenue, Suite 4600
Los Angeles, CA 90071-3197
(213) 229-7000
(213) 229-7520 Fax
www.gibsondunn.com

TRANSFER AGENT & REGISTRAR

Mellon Investor Services
P.O. Box 3315
South Hackensack, NJ 07606-1915
www.mellon-investor.com
(800) 851-9677
TDD – Hearing Impaired (800) 231-5469

SHAREHOLDER RELATIONS

Allen & Caron, Inc.
18300 Von Karman, Suite 410
Irvine, CA 92612
(949) 474-4300
(949) 474-4330 Fax
www.allencaron.com

CURRENT ANALYST COVERAGE

Gruntal & Co.
H.C. Wainwright & Co., Inc.
UBS Warburg

	HIGH	LOW
2000		
[illegible]	$ 24.25	$ 12.88
[illegible]	18.81	8.63
[illegible]	18.25	9.25
October 1, 2000 - December 31, 2000	10.38	1.56
2001		
January 1, 2001 - March 31, 2001	$ 6.75	$ 2.56
April 1, 2001 - June 30, 2001	7.15	3.35
July 1, 2001 - September 30, 2001	6.49	2.80
October 1, 2001 - December 31, 2001	5.03	3.00

The table above sets forth the high and low sales prices reported in each quarter of 2000 and 2001.

MARKET INFORMATION

The Common Stock of ChromaVision Medical Systems, Inc. is traded on the Nasdaq National Market under the symbol CVSN. As of April 12, 2002, the Company had outstanding 20,278,843 shares of common stock held by approximately 11,000 stockholders including beneficial owners of the common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries. The last sale price reported for the Company's common stock on April 12, 2002 was $4.78. The Company has not paid cash dividends and does not anticipate paying cash dividends in the foreseeable future. The Company expects to utilize future earnings to finance future growth.

ANNUAL MEETING

The Annual Meeting of Stockholders will take place on June 5, 2002 at the Hyatt Regency Hotel in Irvine, California. The meeting will convene at 8:30 a.m. All stockholders are cordially invited to attend. A formal Notice of Meeting, Proxy Statement and Proxy will be sent to stockholders of record as of April 12, 2002. The Company has filed an Annual Report on Form 10-K with the Securities and Exchange Commission. Copies of this report including the financial statements and related schedules may be obtained by contacting Allison Wlodyka at ChromaVision Investor Relations at the Corporate Office address listed below.

CORPORATE OFFICE

33171 Paseo Cerveza, San Juan Capistrano, CA 92675-4824
(888) 443-3310 Toll Free (949) 443-3355 Tel. (949) 443-3366 Fax

INTERNET WEBSITE

Information regarding ChromaVision Medical Systems, Inc. and the ACIS® system is available on the Company's Internet website at http://www.chromavision.com.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

Mark One

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For The Fiscal Year Ended December 31, 2001

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from to

Commission File Number 0-1000

CHROMAVISION MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**75-2649072**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification Number)**
33171 Paseo Cerveza San Juan Capistrano, CA	**92675-4824**
(Address of principal executive offices)	**(Zip code)**

(888) 443-3310
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
NONE

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.01
Rights to Purchase Series C Preferred Stock

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days Yes [X] No [ ]

Indicate by check mark if the disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Based on the closing sales price of March 11, 2002 the aggregate market value of the voting stock held by non-affiliates of the registrant was $101,293,720.

The number of shares outstanding of the registrant's Common stock, $.01 par value was 20,258,744 at March 11, 2002.

DOCUMENTS INCORPORATED BY REFERENCE

Location in Form 10-K	Incorporated Document
Part III: Items 10, 11, 12 and 13	Proxy Statement for 2002 Annual Meeting of Shareholders

TABLE OF CONTENTS

Statements in this report describing our plans, goals, strategies, intentions, expectations and anticipated events are forward-looking statements. Important factors which could cause actual results to differ materially from those described in such forward-looking statements include the following: commercialization of our products is dependent on acceptance by the medical community and continued receipt of satisfactory reimbursement from third-party payers; any future success depends upon our ability to expand our sales and marketing organization and to successfully manufacture products in commercial quantities; we will require additional financing for our business, and it is uncertain whether the financing will be available on favorable terms or at all; we may encounter unanticipated expenses, liabilities or other adverse events affecting cash flow; our ability to develop new applications depends on successful collaboration with third parties that we do not control; an inadequate supply of biological samples could delay completion of clinical trials for new applications for our Automated Cellular Imaging System ("ACIS"); the clinical trials could fail to demonstrate the efficacy of the ACIS for new applications; new applications may not be successfully developed; the ability to commercialize new applications may be dependent on obtaining appropriate U.S. Food and Drug Administration (the "FDA") and foreign regulatory approvals and clearances, which may not be obtained when anticipated or at all; manufacture of the ACIS is subject to FDA regulation and our ability to implement our strategy of providing decentralized ACIS analysis capabilities over the internet is dependent upon successful development of the related imaging technology and obtaining any required regulatory approvals. Recent experience with respect to ACIS placements, new contracts for placements, revenues and results of operations may not be indicative of future results for the reasons set forth above.

PART I

Item 1. Business

The Company

We develop, manufacture and market the ACIS®automated cellular imaging system, which is designed to substantially improve the accuracy, sensitivity, and reproducibility of cell imaging. Unlike manual methods of viewing and analysis, ACIS combines proprietary, color-based imaging technology with automated microscopy to assist the pathologist to rapidly make critical medical decisions. In July 1999, the FDA granted clearance for use of the ACIS system to assist the pathologist to detect, count and classify cells of clinical interest based on recognition of cellular objects of particular color, size, and shape.

Industry Overview

A critical aspect in diagnosing disease and making treatment decisions for patients with diseases such as cancer, infectious disease, cardiopulmonary and genetic disorders is identifying cells and organisms that have specific characteristics. Generally this is done using manual microscopy in which a test is performed by a laboratory professional on specimens taken from patients. These specimens are placed on slides and are stained to permit a pathologist to distinguish features of the cells having diagnostic significance. These tests often require precise quantification of the number of affected cells in a sample or the intensity of color of these stained cells. The inability to precisely and reproducibly quantify the result may cause misdiagnosis or inappropriate treatment recommendations.

Manual microscopy works well for simple diagnoses and for cases where disease is obvious; however, manual microscopy can be laborious and subjective. Pathologists often need to review samples containing a large number of cells, ranging from several thousand to millions of cells. It can be difficult to identify rare events, such as finding a few cancer cells in a patient sample containing millions of cells. For example, data submitted to the FDA in our regulatory filing showed that pathologists using manual microscopy correctly identified positively-stained cells in a bone marrow specimen in only 49% of the cases, as compared to 100% for the same pathologists using the ACIS.

Newer diagnostic tests also require pathologists to quantify the intensity of the stained molecules or cells in a patient sample. One of these tests is designed to detect over-expression of the HER2 protein, a protein that has been shown to be an indicator of particularly aggressive breast cancer. Quantification of the stain's intensity is accomplished using a scoring system to determine the recommended course of treatment, but precise determination and quantification of a stain's intensity is difficult. Using manual microscopy, this testing may be subjective because it relies on the human eye, which, even with the aid of a microscope, has limited ability to discriminate between slight color variations in patient samples. Numerous studies have cited this problem, including one in the FDA submission by Genentech, Inc. for Herceptin, a new cancer drug, which is prescribed to patients with over-expression of the HER2 protein. A study published in proceedings of the U.S. and Canadian Academy of Pathology showed that in as many as 41% of

the cases, different pathologists scoring the same stained slide reported scores that would have resulted in a different Herceptin treatment recommendation. An inappropriate treatment regimen can be expensive and may have physical side effects to the patient, including cardiac toxicity. The accelerating development of new therapeutics targeted at genes and proteins will also increase the demand for highly specific and sensitive tests to identify targeted cellular characteristics of biological specimens.

A significant need exists in the laboratory testing market for a standardized system for slide and cell-based tests that will improve the accuracy and consistency of test results. This is one of the last areas within the laboratory where physicians still read and analyze tests manually, where standardization is minimal, proficiency testing is not routinely practiced and inter-laboratory controls are seldom used. These testing limitations have resulted largely from a lack of enabling technology.

Other technologies, such as flow cytometry, fluorescence in-*situ* hybridization (FISH) and polymerase chain reaction (PCR), are used to provide quantitative or semi-quantitative results. These methods however, can be complex, suffer from an inability to directly visualize the molecules or cells of interest and destroy the sample in order to analyze it.

The ACIS Solution

The ACIS is designed to complement the skills of pathologists by assisting them in generating more accurate, specific and reproducible results and reducing the subjectivity associated with current manual testing methods. Our system provides the following solution:

Increased Sensitivity. In a validation study included in our FDA submission, the ACIS showed a 300% increase in detection sensitivity over traditional manual methods. In a separate internal study, the ACIS was able to reproducibly find one cytokeratin-positive cell among a sample containing over 100 million cells.

Flexibility. The ACIS can be used to assist in the analysis of a wide range of diseases by identifying and quantifying a variety of stains and staining characteristics used to identify and evaluate diseased cells. In addition, the system's color-recognition technology allows the ACIS to be configured to be compatible with most reagents and stains that have been developed in the industry.

Reproducibility and Direct Visualization. The ACIS provides a very high degree of reproducibility. In clinical trials, the ACIS instruments reproduced results with 95% consistency, compared to the 72% reproducibility of manual microscopy. In addition, the ACIS system allows for the digital storage of high-resolution images of patient samples, which can be later accessed and revisited by pathologists or treating physicians. The system also has the ability to generate a patient report in both electronic and hard copies for transmittal and review by the physician, a feature unavailable with manual microscopy.

Standardization. The reproducibility attained by the ACIS provides the opportunity for multiple laboratories or multiple pathologists to arrive at consistent results. Currently, standardization of results with manual microscope analysis is minimal.

Automation. The ACIS provides a high degree of automation to the testing process. Up to 100 patient samples can be loaded and scanned unattended for review by a pathologist at a later time, enhancing the workflow of laboratory testing.

Corporate Strategy

Our goal is to establish the ACIS system as the preferred imaging platform to assist in cell-based analysis in the healthcare industry. Using ACIS as an enabling platform, we intend to enhance standardization in laboratory testing by providing an integrated testing system optimized for imaging with the ACIS. In pursuit of that goal, we will:

- continue to offer the ACIS system to customers, including large national reference laboratories, on a fee-per-use basis to maintain a recurring revenue stream while eliminating capital expenditure barriers and obsolescence concerns;
- continue to offer a modified ACIS workstation to lower volume hospitals and laboratories on a fee-per-use basis wherein slide preparation, staining and analysis are performed at a ChromaVision certified laboratory or imaging center and customers then review the resulting images using a remote workstation;
- continue our outreach to biopharmaceutical companies to collaborate in using ACIS for drug discovery and development;

- use the flexibility of the ACIS platform and our 1999 FDA clearance to develop and commercialize numerous applications of our technology;
- continue to expand our direct sales and marketing organization; and
- continue to collaborate with customers, leading pathology testing centers, opinion leaders and other third parties to assist in developing applications for the ACIS and enhance our marketing and distribution capabilities.

There is considerable uncertainty as to whether these strategies can be implemented successfully, and ChromaVision cannot assure investors that it will be successful in doing so.

Business Segments

Segment and geographic area information for the three years ended December 31, 2001 is incorporated by reference from Note 9 "Business Segments," of the Notes to the Consolidated Financial Statements.

ChromaVision's ACIS

Product Description and Benefits

The ACIS combines color-based imaging technology with a fully automated, computer-controlled microscope system. The ACIS uses specifically developed software to analyze specimens placed on slides and stained with laboratory reagents that impart color to highlight diagnostic features of cells. The ACIS uses color as the primary means of detecting and characterizing cellular features. It achieves greater sensitivity than existing methods through its ability to discriminate among millions of colors and up to 256 levels of intensity of each color.

The ACIS system is able to find specific types of cells, count them and, with the assistance of the pathologist, determine the amount of clinically relevant substances on or in the cells. The system does this by automatically scanning the slides with random access, initially at a low magnification, to identify targeted cells using color characteristics. The ACIS then re-images the targeted cells at a higher power and, using additional color criteria and pattern recognition software, displays the relevant cells. The ACIS then generates a report created by the pathologist that can be printed or sent electronically over intranet systems. The report includes information which quantifies the number of affected cells in a sample or the intensity of the stain as well as high-resolution color images of the clinically significant cells. In some competing technologies, the creation of a numeric value destroys the actual specimen being analyzed, preventing further visual review of the specimen. The ACIS, however, creates a permanent visual archive of the results and enables the healthcare practitioner to see the intact cells containing the information needed to guide therapy. This allows laboratory professionals to verify test results and consistently provide more accurate and specific information to the physician.

We offer our customers an entire testing system, including an intelligent, automated microscope, specialized proprietary software, particular staining and slide preparation techniques that utilize marketed reagents, training and service. The ACIS is designed to enable a laboratory technician to operate the system using simple "point and click" commands to scan up to 100 patient samples with fully automated, walk-away operation. The reagents required to perform the tests are presently purchased by the customer from third parties, but we plan to provide ChromaVision-branded reagents for tests most often performed by customers through an OEM arrangement with Richard-Allan Scientific Company, a subsidiary of Apogent Technologies. We also intend to provide a ChromaVision branded auto-stainer to customers to enhance workflow and improve quality control. This is also through an OEM arrangement with Richard-Allan Scientific. The hardware of the ACIS system includes a computer with a modem and monitor, a camera and an automated microscope. Ancillary equipment may include a cover slipper, auto-stainer, slide preparation equipment, hand held bar-code reader and color printer. Our newly introduced product, the ACIS remote pathology workstation, is comprised of all of the hardware and software of the ACIS system with the exception of the microscope component. The ACIS hardware configuration is modular, which means that we can replace most of the individual components without replacing the entire system. This allows us to take advantage of technological advances more easily and reduces the risk of obsolescence. As faster computer processors and increased disk storage become available, those enhancements will improve our product and in many cases lower its cost.

ACIS Applications

The ACIS has four significant and unique capabilities: (1) rare event detection, (2) counting, (3) scoring and (4) analysis of the form and structure of the cell or molecule being examined. The applications being performed by ChromaVision customers use some or all of these features. Our technology, coupled with our existing FDA clearances gives us a significant competitive advantage with respect to our customers ability to identify and add any applications to the ACIS that they currently perform using manual microscopy. Because most laboratory tests require one or more of these unique features, we believe the menu of applications being run on ACIS will continue to expand. Currently, customers have the ability to validate new applications using existing capabilities of the ACIS technology requiring little or no modification to the system. Examples of tests currently being run by our customers include:

HER2 Protein Expression. In performing this test, the pathologist must measure the quantity of the HER2 protein on the cell surface. An excess quantity of HER2 is associated with aggressive breast cancer, faster disease progression and shorter overall survival. Candidates for the new cancer drug Herceptin, which was approved by the FDA and is marketed by Genentech, Inc., must be tested for excess quantities of HER2 to determine whether this therapy should be administered. Currently the test is performed manually, which can result in significant variation of results among individual laboratories and pathologists. A side effect of Herceptin, if it is prescribed under circumstances where it is not appropriate, is cardiac toxicity. In a clinical study, pathologists using the ACIS as a tool were able to reproducibly quantify the amount of protein on the cell surface in over 90% of cases. Pathologists assisted by the ACIS have the potential to substantially improve the accuracy and standardization of test results.

In a published study, ten pathologists reviewed biopsy specimens obtained from 129 breast cancer patients with and without ACIS assistance. The data showed that every pathologist in the study improved his or her performance using the ACIS. As a group, the pathologists improved the reproducibility of their HER2 protein measurements from 75% without ACIS assistance to 95% when using the ACIS. In a different published study of 189 patient biopsies, pathologists using the ACIS found that 38 patients who had been classified as positive for HER2 protein overexpression by manual analysis alone (i.e. without ACIS assistance) were actually negative and should not therefore be exposed to the high cost and potential toxicity of Herceptin therapy.

Estrogen Receptors (ER). The estrogen receptor assay is ordered by physicians for virtually all new cases of breast cancer to assess patient prognosis and to guide clinical decision-making. Patients who are estrogen receptor positive may be candidates for anti-estrogen hormonal therapies such as Tamoxifen. Using manual microscopy, it is difficult to reproduce results between pathologists and laboratories because of the lack of standardized scoring techniques and the subjective nature of test evaluation. A pathologist using the assistance of ACIS is able to provide an objectively scored result, enabling the physician to better identify patients who would benefit from hormonal therapy.

Progesterone Receptors (PR). The progesterone receptor assay is similar to the estrogen receptor assay in that it predicts response to hormonal therapies in certain cases of cancer. Most studies show that when patients' tumors are positive for estrogen and/or progesterone receptors, patients are more likely to respond to systemic hormonal treatments. Because the two assays are highly complementary, physicians routinely order both tests for their newly diagnosed breast cancer patients. The benefits afforded by the PR test using the assistance of ACIS are similar to those discussed above for the ER test, enabling physicians to better identify patients who would benefit from hormonal therapy.

Cell-proliferation (Ki-67). Ki-67 is an antibody recognizing a protein which serves as an indicator of tumor proliferation and, by extension, of tumor growth and aggressiveness. Ki-67 testing is performed upon relatively small biopsy specimens, such as those, which are obtained by fine needle aspiration of mammographically detected breast and other lesions. Ki-67 testing is also performed currently for other diseases such as ovarian, prostate, lung, and colorectal cancers and non-Hodgkin's lymphoma. Manual microscopy is difficult for this test because of the necessity for precise quantification of cells expressing this protein. The ability of the ACIS to assist the pathologist in providing a precise measurement will enable the treating physician to avoid unnecessary chemotherapy regimens and guide alternative treatment options.

Protein expression (p53). p53 is the most commonly altered (or mutated) gene in cancer. Over-expression of the p53 protein indicates whether mutation has occurred in the gene. Further, overexpression of p53 is recognized as an indicator of aggressive cancer even in the absence of gene mutation. This information can be used in cancer staging to assess risk of recurrence and potentially to evaluate cancer risk. p53 can be applied to multiple cancer types. Pathologists using the assistance of ACIS to perform p53 testing will assist in guiding treatment and avoiding unnecessary chemotherapy.

Micrometastases in Bone Marrow. This test involves finding minute quantities of cancer cells in bone marrow, which have been shown to be an early indication of cancer that has metastasized. Testing for small quantities of cancer cells also can be used to monitor the progress of the disease and to provide required information in connection with stem cell and bone marrow transplants. Using manual microscopy, the search for rare events is difficult and often not reproducible. By using the assistance of ACIS, physicians can more accurately monitor cancer progression, make better decisions regarding the best course of therapy and evaluate a patient's response to therapy.

Micrometastases in Tissue. This test is now being used to evaluate lymph nodes in breast cancer patients. This test is recommended for nearly all breast cancer patients and is expected to have broad applicability to multiple cancer types including skin, thyroid, head and neck, gastrointestinal and gynecologic cancers. The ACIS can provide significantly greater sensitivity, accuracy and reproducibility to a test that is potentially inaccurate and tedious when performed manually. Test data demonstrated that utilizing the assistance of the ACIS makes it practical to examine a greater number of tissue sections than the manual method, increasing the likelihood of detecting metastases if they are present.

Tissue Microarray. Tissue microarray technology enables the analysis of hundreds of samples simultaneously in a single display and has emerged as a valuable new technique used by biopharmaceutical companies to facilitate new drug discovery. This technique realistically enables a full clinical trial to be performed on one single slide and enables data comparisons never before possible. Using the assistance of the ACIS, analysis that would take many hours or days to perform manually can be performed in only minutes, saving time for clinicians and advancing the availability of completed study data.

Research Use Only Applications

The following tests have been developed for use with the ACIS and are presently used for research purposes only.

DNA Ploidy. This test quantifies DNA in cell nuclei and is an important component of the primary panel of tests performed to characterize tumors and determine the aggressiveness of those tumors. The ACIS DNA Ploidy test minimizes the subjectivity in analysis and assists pathologists and oncologists in being more certain of their treatment decisions. The ACIS is able to collect more information at a rate five times faster than older-generation image analysis systems used for DNA Ploidy testing.

Vascular Density. This test assists pathologists in determining the density of new blood vessels. Numerous studies indicate that elevated tumor vascular density correlates with poor prognosis for a spectrum of solid tumors and may therefore be useful for guiding therapeutic intervention. In particular, the ACIS-assisted test may be of particular value in identifying patients who are candidates for novel anti-angiogenesis/anti-vascular agents. Animal studies suggest that this category of emerging therapeutics may be particularly effective for tumors with high vascular density. We anticipate partnering with more pharmaceutical companies to ascertain the predictive value of our vascular density assay for anti-angiogenesis therapy in upcoming months.

EGFR. Epidermal growth factor receptor (EGFR) is a receptor protein that is overexpressed in greater than one third of all human solid tumors. Our test determines the presence of and quantifies the level of EGFR expression. Based on the fact that this protein is commonly overexpressed in carcinomas, it has been the target for molecular therapeutic testing within the biopharmaceutical industry. One good example is a monoclonal antibody-based therapeutic IMC-C225, developed by ImClone Systems, Inc. Other emerging therapies are ZD 1839 (Iressa, AstraZeneca) and Tarceva (Genentech, Inc.) which selectively block EGFR signaling pathways that are implicated in cancer cell growth and survival. These therapeutics are currently in clinical trials for the treatment of non-small cell lung cancer and other malignancies.

Applications UnderDevelopment

The ACIS system capabilities are flexible and readily adaptable to numerous applications. We work actively with our customers to rapidly develop, validate & implement new applications using these existing capabilities. We maintain a queue of prioritized development applications based on specific criteria. Currently, customers are using tests related to cancer such as prostate, colon and stomach cancers, but system capabilities could also be applicable to infectious disease and genetic testing. Key development applications with short- and long-term potential include a lymphoma panel consisting of 3-15 tests and rare-event detection capabilities applied to detecting circulating tumor cells in peripheral blood. The following is a description of some of the tests that are currently being developed:

Immuno Phenotyping-Lymphoma. Lymphoma is a term used to describe a group of about thirty different cancers of the lymphatic system. In this group of diseases one of several types of "white blood cells" (the cells involved in fighting infection) multiplies uncontrollably. Frequently, lymphoma is first detected in one or more lymph nodes, which can become swollen. More advanced disease may also involve extranodal sites such as visceral organs, bone marrow, or spinal fluid. Although there are many subclassifications of lymphoma, a broad distinction is made between two main types. One type is called Hodgkin's disease, and the second is all other lymphomas, which are grouped under the category non-Hodgkin's Lymphoma. There are large differences in response to treatment depending upon the type of lymphoma that is involved. There are also large differences in patient survival. An accurate assessment is therefore essential for prognosis and treatment decisions. ACIS-assisted analysis provides a new integrated approach that facilitates analysis of certain tumor features relating to the body's immune system. Direct visualization and enumeration of certain specific cell populations can be achieved in diagnostically informative anatomical regions of the lymph node specimen.

Circulating Tumor Cells in Peripheral Blood. This test is used in the laboratory to identify circulating tumor cells at very low frequencies and has the potential to be used to diagnose cancer at an earlier stage than is presently possible. The test may determine whether chemotherapy should be undertaken and also whether a patient is responding to chemotherapy. This test is presently only performed manually in academic research centers and biopharmaceutical companies. Using the assistance of ACIS to identify-rare event tumor cells circulating in the blood has potential application in therapeutic monitoring and, more importantly, as a screen for at-risk individuals for multiple cancer types. We have completed a pilot study with the Mayo Clinic involving 93 individuals (65 with breast cancer and 28 cancer-free) which indicated that the test is both feasible and very specific. The test, which was performed by clinical investigators who were blinded as to the source of the patient sample, found tumor cells only in the patients with cancer and never in the cancer-free individuals. We are pursuing additional studies and are in the final phase of a clinical study to compare the sensitivity of the ACIS test to other existing techniques, including mammography.

Fetal Cell Analysis. This test is used in the laboratory to identify and count very rare blood cells from the fetus, which are present in the mother's blood stream. Women bearing a fetus that is genetically abnormal (e.g., Down syndrome) are known to have elevated numbers of fetal cells in their bloodstream relative to women with normal pregnancies. Enumerating and characterizing rare fetal cells has the potential to provide a new, non-invasive means to screen for Down syndrome and other genetic abnormalities in the fetus. A successful screening test for Down syndrome could prevent unnecessary amniocentesis--a procedure that, while considered safe, nonetheless results in a significant risk for both miscarriage and post-amniocentesis complications for the fetus. We have successfully identified and enumerated nucleated fetal cells in the bloodstream of pregnant women in pilot studies. We believe that our assay has the potential to significantly reduce the morbidity and mortality associated with amniocentesis. We anticipate pursuing a corporate partner to further explore the clinical value of this novel minimally invasive test.

Cell-based HIV Viral Load. Currently, the assay used in the laboratory to monitor the efficacy of antiviral therapy, called the serum-based viral load test, measures the quantity of virus in the serum of infected patients. This test is not very sensitive, and after the initiation of therapy, the load of virus in the serum rapidly drops to an undetectable level. It is known that the virus replicates, or grows, within white blood cells of infected individuals. There is, therefore, a clinically significant reservoir of rare infected cells that ultimately sustains or maintains HIV disease. The direct measurement of these presently undetectable HIV-infected cells may provide physicians with a far better means to monitor response to therapy and possibly lead to total elimination of the disease. Working with investigators at the University of California at Los Angeles, we have developed a test using ACIS to assist in identifying and enumerating rare white blood cells from patients infected with the HIV virus. Following the experimental introduction of the virus to cells in the laboratory, this test has been very effective in identifying and enumerating the virus-infected white blood cells and resolving them from non-infected cells. We are now testing the feasibility of this assay on blood samples from HIV patients and will be exploring several approaches for the optimal analysis of HIV-infected cells. We anticipate engaging in a larger clinical trial to begin to evaluate the clinical utility of this test. This test is not being performed today except in research centers.

Collaborations

We have entered into an agreement with Richard-Allan Scientific Company, a subsidiary of Apogent Technologies Inc., to develop and market ChromaVision-branded reagent kits and antibodies used in immunohistochemical (IHC) testing and to develop and market a ChromaVision-branded autostainer. These products are intended to complement and be marketed along with the ACIS system. These complementary products will be designed to bring enhanced quality control and standardization to IHC procedures, one of the most widely used methodologies in laboratory testing. Although the ACIS system can be used with commercially available stains and stainers, the new ChromaVision products will be optimized for image analysis on the system. The combination of these

specialized reagent kits and the ACIS digital microscope system will provide laboratory and pathology customers with an integrated laboratory testing tool to address the growing need for quantitative, standardized IHC testing information.

We have entered into an agreement with Abbott Laboratories to support the clinical development of Abbott's cancer compounds targeting tumor angiogenesis. The ACIS system and ChromaVision-labeled antibodies and reagents will be employed in the research and assessment of the efficacy of Abbott's developmental anti-angiogenic compounds. Abbott will provide samples from clinical trial patients with multiple cancer types and at various stages of progression to understand and evaluate the scope of patient response. Data gathered through the collaboration will be used by Abbott to support clinical development.

We have entered into a co-marketing agreement with US LABS, Inc., a full service, national reference laboratory with a sales force of over 50 individuals across the country. US LABS is an accredited ACIS imaging laboratory that services remote pathology ACIS users by performing the technical and professional component of analysis. US LABS provides laboratory staining services and ACIS image scanning to hospital-based pathologists who then use their own ACIS remote viewing systems to assist them in interpreting the digital images. The program has been highly successful for US LABS and for ChromaVision and will likely be expanded in 2002.

We have entered into and will continue to use scientific collaborations to assist in developing our application menu and enhancing our marketing and distribution capabilities. We collaborate with customers as well as researchers at prestigious hospitals and major laboratories to assist with clinical studies and publishing peer reviewed scientific papers.

Additionally, we will be seeking to collaborate with companies who can create greater awareness and/or distribution capabilities to accelerate our business plan.

Sales & Marketing

Our goal is to make ACIS and the remote pathology workstation technologies available to the entire clinical laboratory market. To accomplish this, the ACIS and the remote pathology workstation are marketed under various revenue models.

Fee-Per-Use Model

The ACIS and the remote pathology workstation are offered under lease arrangements in which the customer is charged based on the number of tests performed, subject to a minimum monthly payment. Rather than selling the systems, our fee-per-use strategy removes any capital equipment investment barrier to new system placements, shortens our placement cycle, yields very attractive margins and gives us a continuing source of revenues. The fee-per-use is determined by the specific test that is run along with the volume of tests run. On a monthly basis, we poll each customer's instrument by modem to retrieve usage information. The list prices of our tests range from $75 to $150.

Direct Sales

We strategically sell the ACIS to research market customers, and will either sell or lease the system on a fixed rent basis in the European Community where the fee-per-use strategy is not accepted in the international healthcare structure.

Customers

Our target customers fall broadly into two principal market segments. We direct our marketing efforts to the following groups of customers that perform laboratory testing:

Clinical Market

Reference laboratories. These laboratories have a national presence or specialized focus and include Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings and Specialty Laboratories Inc.

Pathology practice groups. These groups network individual pathology practices nationally or regionally. The majority of practicing pathologists are members of one of these groups.

Hospitals. This segment is comprised of community or regional hospitals and regional cancer centers. The majority of slide-based testing is currently done in hospitals, and the second largest category for testing is reference laboratories.

Research and Biotechnology Market

Pharmaceutical companies. These companies benefit by using the ACIS in the drug development process. In addition, the ACIS may assist in directing the treatment protocol for patients with new therapeutics, such as Herceptin and anti-angiogenesis agents.

University medical centers. These medical centers include transplant, oncology and research centers as well as AIDS specialty, pre-natal specialty and women's hospitals.

Research institutions. These institutions include governmental sanctioned groups such as The National Cancer Institute, The National Institutes for Health and the Center for Disease Control as well as cancer cooperative groups such as the ECOG, NSABP and SWOG.

ACIS systems have been placed in each of these markets in the United States. We estimate that in the U.S. there are up to 4,000 potential customers in these groups.

As of December 31, 2001, the sales and marketing organization consisted of 33 people, including 14 direct sales people and nine technical service specialists in the United States and three direct sales people and two technical service specialists in Europe. We expect that the majority of our sales will result from direct, face-to-face selling efforts by our sales force augmented by strategic collaborations. As a result, we intend to devote significant resources to our sales and marketing organization to support the acceleration of the commercialization of our products, principally to hire additional direct salespeople but also to hire additional service specialists.

We have entered into agreements with independent distributors to market the ACIS in Italy, Scandinavia and the Benelux countries. We have established direct sales subsidiaries in Germany and France, which market the ACIS in those countries and in the rest of Western Europe.

Reimbursement Strategy

Our product pricing reflects both the value that our ACIS technology brings to the healthcare system and the direct and indirect costs of providing the technology to healthcare providers. Our pricing does not derive from rates of reimbursement available to our customers from third party carriers. Neither do our customer contracts link payments to ChromaVision with customer collections from patients or third party carriers. However, reimbursement continues to play an important part in our marketing success. Laboratory services provided for patients with the assistance of our ACIS technology are eligible for third party reimbursement under pre-existing medical billing codes. These billing codes are known as Common Procedural Terminology, or CPT, codes and are the means by which Medicare and private insurers identify every medical service that is likely to be provided to patients in the U.S. Using well-established CPT codes to bill for their ACIS-based services, laboratories and pathologists qualify for payments from the carriers at rates which are incrementally higher than those available to healthcare providers who provide similar services but do so by means of manual microscopy alone, that is, without ACIS assistance.

CPT codes are established by the American Medical Association. The reimbursement dollar amount associated with each CPT code is established jointly by the U.S. Centers for Medicare and Medicaid (CMS, formerly the Health Care Finance Administration), private insurers, and representatives from the AMA. Our ACIS technology is eligible for billings under CPT codes assigned for use with quantitative image analysis.

Data from published studies have shown that pathologists can use ACIS to help themselves improve in identifying patient candidates for emerging, protein-targeted therapies such as Herceptin. Using data from these studies, it is possible to demonstrate a direct cost-benefit potentially accruing to the healthcare finance system through ACIS use.

In the fourth quarter of 2001, use of the ACIS was reviewed independently by three large insurance companies in the Northeastern United States that act as administrators for Medicare programs in their respective states. We provided the medical directors of these insurance companies with information that detailed ways in which physicians were using the ACIS as a tool in their laboratory testing. Based upon their reviews, the medical directors have indicated that they are preparing written policies that will support continued coverage for ACIS-based testing.

Not all carriers undertake such detailed reviews of the ACIS. Most ACIS-based tests are paid routinely because they qualify for reimbursement under existing CPT billing codes. However, every carrier that has rigorously scrutinized ACIS-assisted testing has concluded that its use is appropriate, medically necessary, and that it brings quantifiable economic value to the healthcare system.

Patents and Proprietary Technology

We file patent applications to protect technology, innovations and improvements that we consider important to the development of our business. Currently, we have twelve patent applications pending with the U.S. Patent and Trademark Office and twenty-one foreign patent applications pending. We have received a notification of allowance for one patent for method and apparatus for automated image analysis of biological specimens, and have also received a final issuance for four patents related to the system and method for cellular specimen gradings performed by the ACIS. The patents for which we have received a final issuance have a remaining duration varying from 15 to 16 years.

In all our patent applications, we have endeavored to file claims which cover the underlying concepts of the unique features of the ACIS, its associated processes and methodologies as well as our specific implementation of those processes and methodologies. As a further protection against efforts to evade our proprietary position, we have systematically explored other designs, which could achieve results similar to the ACIS and prepared patent applications on those alternate designs.

We also rely on trade secrets and proprietary know-how that we seek to protect in part through confidentiality agreements with our employees and consultants. As a condition of employment, we require that all full-time and part-time employees enter into an inventor assignment and non-disclosure agreement.

Though not currently involved in litigation regarding our proprietary technology or the proprietary technology of others, we intend to aggressively protect our rights. We also intend to broaden the scope of our intellectual property portfolio, which we consider critical to our future product development. If we are unable to protect our patents and proprietary rights, our reputation and competitiveness in the marketplace could be materially damaged. Litigation may therefore be necessary in order to enforce any patents that we now hold or that are issued to us. We may also be forced to protect our trade secrets or know-how we own or to determine the enforceability, scope and validity of the proprietary rights of others. It is also possible that others will assert claims against us. The outcome of such intellectual property litigation is inherently unpredictable, such litigation is expensive and the cost and resolution of these matters could materially affect our results and business operations. Moreover, there can be no assurance that the steps we take to protect our proprietary rights will be adequate or that third parties will not infringe, design around, or improve upon our proprietary technology or rights.

Competition

The predominant method of cell-based analysis today is manual microscopy. Our principal competitive objective is to change the traditional way pathologists use manual microscope analysis.

There are companies engaged in developing cell-based diagnostic imaging systems that could compete with the ACIS. Most automated systems do not have the ability to reproducibly find small numbers of cells among a sample containing millions of cells. The rare event detection capability of the ACIS, by using color as its primary discriminate, allows us to target tests that require a high level of sensitivity. Most automated microscopy companies have focused their sales and marketing efforts on a specialized market such as Pap smear tests, where their value proposition is based on labor replacement through automation. The pap testing market is one where reimbursement has traditionally been low. Alternatively, we seek to displace costly and invasive procedures such as surgery or expensive drug regimens by assisting the pathologist in obtaining a more accurate and reproducible result.

Additional sources of competition include alternative diagnostic testing methods such as flow cytometry, fluorescent in-*situ* hybridization (FISH) and polymerase chain reaction (PCR). Flow cytometry involves separating individual cells in blood and analyzing them based on results obtained by passing a beam of light through the cells at a very high speed. PCR involves rapidly replicating small quantities of genetic material to permit analysis by detecting color or electrical charge. Both methods have the disadvantages of destroying the patient sample in the process of analysis and yielding a large number of false positive results. The pathologist has to draw conclusions from data produced by the flow cytometry or PCR process, as opposed to actually seeing the cells of interest. Flow cytometry has not proven to be specific enough for applications such as micrometastases, which involves finding a very small number of cancer cells in a large population of cells. FISH involves using fluorescent antibodies to tag genetic material, either DNA or RNA, and analyzing the result by counting the points of light. Since fluorescence emits a very weak signal, use of the

FISH method is very slow as compared to the ACIS. This method is also tedious and time-consuming for the pathologist to both define areas of interest within the specimen and then manually count the fluorescent signals emitted.

We believe that our proprietary color-based image analysis, the multi-test potential of the ACIS, the significant speed and specificity of ACIS tests and our FDA clearance distinguish us from these other methods.

Service

We offer service and maintenance to ACIS customers as part of the "fee-per-use" pricing structure. We have developed a support, field service and parts distribution plan designed to support the installed base of ACIS systems. This plan will offer the following services as part of the "fee-per-use" structure: (i) installation; (ii) customer training and stain validation; (iii) a 24-hour per day, seven-day per week customer help desk available via a toll free number; (iv) the ability to remotely service ACIS units and load new software via dial-up modems, and (v) on-site field service and parts replacement utilizing regionally based field engineers who are supported by our headquarters development and engineering staff. We are currently solving approximately 93% of customer issues remotely in less than an hour and at initial customer contact. ACIS modules have an uptime rate in excess of 99%, and the mean time between failures is approximately 240 days.

Research & Development

To date, our core competency has been in the area of advanced imaging as applied to the detection and quantification of reagent-stained cellular material. At December 31, 2001 we had 26 employees dedicated to engineering and research and development, including several scientists who hold Ph.D. degrees in various disciplines. Our research and development staff is experienced in the rapid prototyping and development of advanced software-based, electro-optical-mechanical systems. We intend to continue to invest in the recruitment of experienced scientists and engineers with an emphasis on achieving a balance between research and development, innovation and support of focused, market driven requirements. Research and development spending was approximately $6,076,000, $6,897,000 and $6,858,000 in 1999, 2000, and 2001, respectively.

Manufacturing

The ACIS is currently manufactured at our facility in San Juan Capistrano, California. Our employees assemble the components, optically align the microscope, load the software and quality test the system. Components of the system are manufactured internally, purchased off-the-shelf, or manufactured by subcontractors to our specifications. The system uses an off-the-shelf charged couple device (CCD) camera and an Intel/Microsoft-based personal computer. The system can be adapted for use with most popular microscopes and related optical accessories. The ACIS has been designed to be fully modular to take advantage of improvements in microscopy and computer hardware. We are Quality Systems Regulation (QSR) compliant, we achieved International Standards Organization (ISO) 9001 certification and we have received a CE Mark.

Governmental Regulatory Status

As a medical device, our ACIS product is subject to governmental regulation in the United States and in other countries. In the United States, the Federal Food, Drug, and Cosmetic Act (FDC Act), along with the regulations promulgated by the United States Food and Drug Administration (FDA) as well as various other federal and state statutes and regulations, govern the testing, manufacture, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion and importing and exporting of medical devices.

Before a company can place a medical device into interstate commerce for sale in the United States, FDA must review and approve or clear the device unless it is exempt under FDA's regulations. Approvals and clearances are generally for specific intended uses. This regulatory process can be lengthy, expensive and uncertain. Extensive clinical data and other information can be required by FDA in order for the agency to approve or clear a medical device.

Under the FD&C Act and its regulations, medical devices are placed into one of three classes on the basis of FDA's view of their risk and the controls necessary for assuring their safety and effectiveness. These three categories are referred to as Class I, Class II and Class III. ACIS was cleared as a Class II product.

Class I devices are those in the lowest risk category. As such, many Class I medical devices are exempt from certain pre-market and other regulatory requirements. To sell a non-exempt Class I device or a Class II device, a manufacturer must submit and obtain an order from FDA stating that the product is cleared for marketing in the United States. This FDA clearance is achieved through the filing of a Pre-market Notification (510(k)) based on the device being "substantially equivalent" to a legally marketed product, i.e., a Class I or Class II medical device or a Class III device for which FDA has not yet required a Premark Approval application (PMA). Class III devices are those in the highest risk category. As such, a manufacturer must submit and obtain FDA approval of a PMA before the device can be introduced to the United States market. The PMA process is significantly more complex and time-consuming than the 510(k) process. The PMA process almost always requires the submission of well-controlled clinical investigations in order to obtain FDA approval. On average, FDA reviews and clears a 510(k) submission within four months. PMA approval by the agency generally takes at least one year and can even take a number of years. In the case of a PMA and/or a 510(k), there is no assurance that the agency will agree with the submission and/or clear or approve the product. FDA may reject a 510(k) submission and require that a company file a PMA instead. Determination by FDA that any of our devices or applications are subject to the PMA process could have a material adverse effect on our business, results of operations and financial condition. Nonetheless, a business benefit can accrue where FDA approves a PMA because holding a PMA may, in some instances, provide a competitive advantage. A change or modification of a medical device that has already received FDA clearance or approval can result in the need to submit further filings to the agency. A change or modification of a product cleared through the 510(k) process can result in the need for a new 510(k) submission where the change or modification could significantly affect the safety or effectiveness of the device. A change in a device that is the subject of an approved PMA could require a PMA supplement.

We obtained our first 510(k) clearance from the FDA to market the ACIS with a test to screen blood for malignancy. In July 1999 we received our second 510(k) clearance from the FDA which granted use of the ACIS to assist the pathologist to detect, count and classify cells of clinical interest based on recognition of cellular objects of particular color, size and shape.

As a Class II medical device manufacturer, we are also subject to FDA's Quality System Regulation (QSR) which includes FDA's regulatory requirements for Good Manufacturing Practices (GMPs). In addition, we are subject to FDA's regulations regarding labeling, medical device reporting and reports of removals and corrections. The medical device reporting regulations require us to provide certain information to FDA in the event of a death or serious injury allegedly associated with the use of ACIS or any product malfunction which would likely cause or contribute to a death or serious injury if the malfunction were to recur. Class II devices may also be required to adhere to certain "special controls" including but not limited to performance standards, post-market surveillance and/or patient registries where applicable. In addition, we must comply with applicable regulatory requirements for the export of our products.

FDA's QSR requires, among other things, that we have (i) a written quality assurance policy and procedures for controlling and documenting all aspects of our manufacturing processes, (ii) the ability to produce devices which meet the applicable design controls and specifications which have been validated by extensive and detailed review of each of the manufacturing processes, and (iii) the ability to conduct, and written procedures for conducting, corrective and preventative actions. FDA conducts periodic inspections to determine compliance with all of the regulatory requirements imposed by the FD&C Act and its regulations. If deficiencies are noted during the inspection, the FDA investigator may issue FDA Form 483 that lists the observed deficiencies. The State of California Department of Health Services (DHS) enforces that state's requirement that our facility have a Medical Device Manufacturing License. The requirements for that license include adherence to FDA's QSR. Our facility has been inspected by DHS, and we have been issued a license to manufacture devices in California. This license must be renewed every year. The State of California could prohibit our manufacturing of medical devices if we failed to maintain this license.

In November 2000, we received a warning letter from FDA's Center for Devices and Radiological Health (CDRH) which took issue with certain claims being made for our ACIS device. The letter questioned the basis for certain claims and whether certain uses of the device exceeded the scope of FDA's clearance of ACIS. In May 2001, we resolved those issues through a series of communications with the FDA without penalty. As a result of this resolution, we continue to market our product to physicians to detect, count and classify cells of clinical interest based on recognition of color, size and shape. Laws and regulations regarding the manufacture, distribution, marketing, sale and use of medical devices are subject to change and depend heavily on administrative interpretations by federal and state government agencies, including FDA. There can be no assurance that these regulations or their interpretations will not change in the future or that such changes will not be applied retroactively.

We may be subject to a number of other laws and regulations in those states and countries where our products are now or will in the future be marketed. These laws and regulations may restrict or hinder our ability to market our products in those states or countries. Use of our products may be subject to periodic inspection, quality control checks, quality assurance checks, proficiency

testing, documentation and safety reporting standards pursuant to the Joint Commission on Accreditation of Healthcare Organizations, a self-regulated consortium of health care organizations. Depending on circumstances, including but not limited to our strategies and discussions with potential distribution partners, we may develop a distribution strategy that initiates marketing in international markets prior to marketing in the United States.

In anticipation of marketing our products in the European Union (EU) we applied for and received ISO 9001 certification and our ACIS product was CE marked in 1998. The CE Mark was applied after we demonstrated compliance with applicable regulatory requirements, including, but not limited to, compliance with pertinent ISO requirements and certification by a recognized notified body.

Employees

As of December 31, 2001, we employed 99 persons of which 26 persons were in product development and engineering, 25 persons were in manufacturing, quality assurance and field services, 15 persons were in finance, executive and administrative capacities and 33 persons were in sales and marketing. We are not subject to any collective bargaining agreements, and we believe that our relationship with our employees is good.

In addition to full-time employees, we utilize the services of various independent contractors, primarily for certain product development and foreign sales, marketing and administrative activity.

Item 2. Properties

Our executive office, development and manufacturing facilities are located in San Juan Capistrano, California, in approximately 21,000 square feet. We lease the space at an annual rent of approximately $143,000. The existing lease agreement expired on February 28, 2002 and we exercised our final option to extend the lease to February 28, 2003. We are currently exploring leasing other facilities as we anticipate that additional space will be required as the business expands. We believe that we will be able to obtain suitable space as needed.

Item 3. Legal Proceedings

We are not a party to any legal proceedings, the adverse outcome of which, individually or in the aggregate, management believes would have a material adverse effect on the business, financial condition or results of operations of the business.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to us by a vote of the security holders during the fourth quarter ended December 31, 2001.

Executive Officers

The following persons were executive officers of the Company at April 1, 2002:

Name	Age	Position
Douglas S. Harrington, M.D.	49	Chairman of the Board
Carl W. Apfelbach	49	President and Chief Executive Officer
Kevin C. O'Boyle	46	Chief Operating Officer and Chief Financial Officer
Kenneth D. Bauer, Ph.D.	51	Vice President and Chief Science Officer
Michael G. Schneider	52	Vice President of Operations
Jose de la Torre-Bueno, Ph.D.	53	Vice President and Chief Technology Officer
David Weisenthal	52	Vice President of Marketing

Douglas S. Harrington, M.D., 49, Chairman of the Board of ChromaVision, brings over twenty years experience in the commercialization of healthcare technology. Dr. Harrington was President and Chief Executive Officer of ChromaVision from December 1996 until April 2002 and has been Chairman of the Board since June 2000. Prior to joining the Company, Dr. Harrington served as Chairman and President of Strategic Business Solutions, Inc., a privately held company specializing in the commercialization of biotechnology, and as a Principal in Douglas S. Harrington and Associates, a strategic consulting firm. From 1992 to 1995, Dr. Harrington was President of Nichols Institute, a publicly traded healthcare laboratory services provider, now part of Quest Diagnostics, Inc. Prior to 1992, Dr. Harrington held various management positions within Nichols Institute including Vice President of Operations and Medical Director. Dr. Harrington currently sits on the Board of Directors, Advisory Board, or Scientific Advisory Board of several other related healthcare or medical device companies. Dr. Harrington holds a Bachelor of Arts Degree as well as a Medical Degree from the University of Colorado with specialties in Hematology and Anatomic & Clinical Pathology. Dr. Harrington has numerous professional affiliation memberships including the American Medical Association, the American Society of Clinical Pathologists, the College of American Pathologists and the International Academy of Pathology.

Carl W. Apfelbach, 49, President and Chief Executive Officer of the Company since April 2002, was President and Chief Operating Officer from May 2001 until April 2002. Mr. Apfelbach brings over twenty years of clinical diagnostics, laboratory product development and international general management experience to ChromaVision. From December 1994 to December 2000 Apfelbach served as Corporate Vice President with Dade Behring, a privately held provider of clinical and laboratory products. From August 1997 to June 1999, he was President of Dade Behring Limited in Tokyo, Japan. Mr. Apfelbach also spent nearly ten years with Baxter International, a publicly traded worldwide manufacturer and distributor of diversified healthcare products, where he served in various senior management positions, most recently Vice President and General Manager. Mr. Apfelbach holds a Master's Degree in Business Administration in Marketing and Finance from Case Western Reserve University and a Bachelor's Degree in Economics and History from Denison University.

Kevin C. O'Boyle, 46, has been Chief Operating Officer of the Company since April 2002 and Chief Financial Officer since December 1996. From December 1996 to January 1999 he was also a Vice-President, from January 1999 to November 2000 he was Senior Vice-President of Operations and from November 2000 to March 2002 he was Executive Vice President of Operations. From 1990 to 1994, Mr. O'Boyle was the Chief Financial Officer and from 1994 to 1996, he was Sr. Vice President of Operations for Albert Fisher North America, a publicly traded international food company. From 1984 to 1990, Mr. O'Boyle served as the Vice President and Controller of American Cablesystems, a publicly traded cable television firm. He previously held various accounting positions on the audit and tax staff with Pannell, Kerr & Forster, a public accounting firm. Mr. O'Boyle is a CPA and earned a Bachelor of Science degree in Accounting with honors from the Rochester Institute of Technology. Mr. O'Boyle also graduated from the University of California at Los Angeles John E. Anderson Graduate School's Executive Program in Management.

Kenneth D. Bauer, Ph.D., 51, has been Vice President and Chief Science Officer since August 1997. From 1992 to 1997, Dr. Bauer was Senior Scientist in the Immunology Division and head of Cytometry for Genentech, Inc. a publicly traded biotechnology company. Prior to Genentech, Dr. Bauer held academic positions at Northwestern University (Associate Professor of Pathology) and the University of Rochester, in New York (Assistant Professor of Oncology). Dr. Bauer has authored over 90 peer-reviewed scientific publications, edited two books, and was Associate Editor of Cytometry (Journal of the Society of Analytical Cytology) for ten years. Dr. Bauer has been a member of the scientific advisory boards for several public companies and served on scientific review sections for the National Institutes of Health, Department of Energy, and National Aeronautics and Space Administration. He is currently a Clinical Professor of Pathology at the Keck School of Medicine, University of Southern California, an Adjunct Professor of Pathology and Laboratory Medicine at the University of Pennsylvania School of Medicine and a subcommittee member of the National Committee for Clinical Laboratory Standards. Dr. Bauer received a Bachelor of Arts degree in Zoology from the University of California at Los Angeles and a Doctorate of Philosophy in Anatomy and Radiology from the University of Utah.

Michael G. Schneider, 52, has been Vice President of Operations since April 2001, and was Vice President of Manufacturing and Service since June 1996. From 1995 to May 1996, Mr. Schneider was Director of Operations at Kodak Health Imaging Systems, Inc. From 1993 to 1995, Mr. Schneider was Director of Worldwide Service at Kodak's Health Imaging Service Division. From 1990 to 1993, Mr. Schneider was Manager of Electronic Imaging Service Support at Kodak's Health Science Division. Mr. Schneider has over twenty-five years of experience in manufacturing and service management.

Jose de la Torre-Bueno, Ph.D., 53, has been Chief Technology Officer since April 2001, and has been Vice President since February 1999. Dr. Torre-Bueno was also Senior Applications Engineer for the Company from July 1998 to February 1999. Prior to joining ChromaVision, Dr. Torre-Bueno was engaged as a consultant to Tower Technologies in Encinitas, California. In 1982, he founded American Innovision; an image analysis company that configured complete application systems and designed and built

software and hardware. He served as Owner, President, and Vice President of Research and Development for American Innovision, a company in which he had a substantial ownership interest, until its sale to Oncor Instrument Systems in 1992. He remained with Oncor for three years after the sale as Senior Scientist and Research and Development Manager. Dr. Torre-Bueno has been an inventor on two issued patents and one pending patent and has assigned the rights for two additional inventions to ChromaVision. Dr. Torre-Bueno is currently an Adjunct Professor in the Department of Mathematical Sciences at San Diego State University and a Clinical Professor of Pathology at the Keck School of Medicine, University of Southern California. Dr. Torre-Bueno earned a Bachelor of Science degree in Biology and Psychology from the State University of New York at Stony Brook and a Doctorate of Philosophy in Physiology, Behavior and Genetics from Rockefeller University.

David Weisenthal, 52, has been Vice President of Marketing since October 1999 and prior to this was Director of Marketing since September 1998. From 1997 to 1998, Mr. Weisenthal served as Vice President, Marketing at US LABS, Inc., an anatomic pathology reference laboratory. Prior to US LABS, Mr. Weisenthal spent seven years at Oncotech, Inc., an oncology reference laboratory, where he was Director, Corporate Marketing. From 1992 to 1995, Mr. Weisenthal was a partner in an oncology reference laboratory that he co-founded. He also spent seven years in the radio and television industry and served in the United States Army. Mr. Weisenthal earned a Bachelor of Arts degree in English, Marketing and Telecommunications from the University of Louisville.

PART II

Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

Our common stock trades on the NASDAQ National Market under the symbol "CVSN". The table below sets forth the high and low sales prices of the common stock:

	High	Low
January 1, 2000 – March 31, 2000	24.25	12.88
April 1, 2000 – June 30, 2000	18.81	8.63
July 1, 2000 – September 30, 2000	18.25	9.25
October 1, 2000 – December 31, 2000	10.38	1.56
January 1, 2001 – March 31, 2001	6.75	2.56
April 1, 2001 – June 30, 2001	7.15	3.35
July 1, 2001 – September 30, 2001	6.49	2.80
October 1, 2001 – December 31, 2001	5.03	3.00

As of March 11, 2002 we had outstanding 20,258,744 shares of common stock held by approximately 11,000 shareholders including beneficial owners of the common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries.

We have not paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. We expect to utilize any future earnings to finance our operations. The actual amount of any dividends paid would be subject to the discretion of the Board of Directors of the Company and would depend on our operations, financial and business requirements and other factors.

Changes in Securities and Use of Proceeds

On September 28, 2000, we completed a private placement of 560,693 shares of our common stock and warrants to purchase 56,070 additional shares of our common stock to two institutional investors for $7 million. The purchase price per share was $12.48 and was based upon an average of high and low trading prices of our common stock for a 20-day period prior to the sale. Net proceeds were approximately $6.7 million. The warrants have a term of five years and are exercisable at the same $12.48 per share price. The shares were issued in reliance upon the exemption from the registration requirement of the Securities Act of 1933 afforded to transactions not involving a public offering, and the shares issued and issuable upon exercise of the warrants have since been registered for resale under that Act. Of the $7,000,000 purchase price, $5,000,000 was purchased by a wholly owned subsidiary of Safeguard Scientifics, Inc., and $2,000,000 was purchased by VennWorks LLC, formerly incuVest LLC, a private investment fund. Safeguard Scientifics, Inc. already held approximately 27% of our outstanding shares, and VennWorks was also a stockholder.

In January 2001, we entered into a financing agreement with VennWorks LLC providing for VennWorks to invest up to $5 million in our common stock at various dates and in amounts selected by us from March 30, 2001 through December 28, 2001 (subject to certain limitations). The price per share is based upon the average closing price of our common stock on the Nasdaq National Market during a 20-day trading period prior to our request to purchase, subject to a minimum of $7 per share and a maximum of $14 per share. VennWorks has invested $400,000 at a per share price of approximately $7 per share pursuant to this arrangement but has missed other payments due to us. As a result we accelerated the date when the entire balance of the shares were to be purchased. VennWorks failed to complete the purchase and has advised us that it does not have the funds to do so.

On July 10, 2001, we obtained $12.5 million in additional funding through a private placement of redeemable, convertible preferred stock and warrants to seven institutional investors. Halifax Fund LP served as the lead investor of the private placement. Other investors included a subsidiary of Safeguard Scientifics, Inc., currently our largest shareholder. UBS Warburg LLC served as exclusive placement agent for this transaction.

The preferred stock bears a 5% cumulative annual dividend payable in cash or common stock and is convertible into common stock at $6.57 per share. The number of shares of common stock presently issuable upon conversion of the preferred stock is 1,901,256, but that number is subject to adjustment corresponding to adjustments in the conversion price. The preferred stock is required to be redeemed by us three years after issuance for the amount paid for the preferred stock plus accrued and unpaid dividends.

The warrants are exercisable to purchase an aggregate of 546,615 shares of common stock at any time after issuance for a period of five years at a price of $6.86 per share, which represents 120% of the market price of our common stock over a designated period prior to closing. The number of shares issuable upon exercise of the warrants is subject to adjustment corresponding to adjustments on the exercise price. The Company allocated the total amount paid by the investors, net of issuance costs, between the preferred stock, the fair market value of the warrants and the intrinsic value of the conversion feature of the preferred stock. The fair market value of the warrants was determined to be approximately $2,295,000 (using the Black Sholes valuation model). The remaining net amount paid by the investors divided by the number of shares issuable upon conversion of the preferred stock is the effective conversion price of the preferred, and the difference between the fair market value of the common stock on the date of issuance of the preferred and the effective conversion price is the intrinsic value of the conversion feature, which amounted to $1,148,421. The fair market value of the warrants and the intrinsic value of the conversion feature are allocated to paid-in-capital and are accreted (amortized) over the three year period prior to mandatory redemption of the preferred stock. The issuance costs of approximately $1,197,000 are also recorded as a discount to the preferred stock and are accreted over the three-year redemption period.

Under the terms of the transaction documents, the preferred stock is required to be converted into common stock if the trading price of the common stock equals or exceeds 175% of the initial conversion price for 20 out of 30 consecutive trading days occurring after the first anniversary of the purchase of the preferred stock. The conversion price of the preferred stock and the exercise price of the warrants are subject to adjustment upon the occurrence of certain events, including an adjustment after one year if the then current average trading price of the common stock for a designated period is less than the conversion or exercise price, respectively, but the amount of the adjusted price for the one-year adjustment cannot be less than a floor of $4.0019 per share.

Item 6. Selected Financial Data

The following table presents selected financial data for the last five years of the operation of our business. The following information should be read in conjunction with the Consolidated Financial Statements and Notes thereto in Item 8 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7.

	Years Ended December 31,				
	1997	1998	1999	2000	2001
Consolidated Statement of Operations Data:					
Revenue[1]	$ 43,500	$ 16,823	$ 268,720	$ 1,196,153	$ 4,886,352
Selling, general and administrative expenses	3,185,583	4,068,675	6,186,332	9,453,810	10,951,564
Research and development expenses	3,565,331	4,664,311	6,075,835	6,897,377	6,857,627
Net loss[2]	(6,343,927)	(8,078,325)	(11,560,830)	(14,752,476)	(13,641,150)
Accretion of and dividends on redeemable, convertible preferred stock[3]	—	—	—	—	(1,006,081)
Net loss attributable to common stock	$ (6,343,927)	$ (8,078,325)	$ (11,560,830)	$ (14,752,476)	$ (14,647,231)
Basic and diluted net loss per common share[2]	$ (0.47)	$ (0.47)	$ (0.64)	$ (0.75)	$ (0.73)

	As of December 31,				
	1997	1998	1999	2000	2001
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 12,926,398	$ 2,853,546	$ 11,802,668	$ 9,797,698	$ 7,401,078
Total assets[4]	22,249,016	14,630,955	22,434,855	14,901,546	15,065,221
Total liabilities[5]	878,720	1,243,735	1,314,797	1,690,159	12,508,317
Accumulated deficit	(15,149,947)	(23,228,272)	(34,789,102)	(49,541,578)	(64,188,809)
Total stockholders' equity	21,370,296	13,387,220	21,120,058	13,211,387	2,556,904

(1) Revenue includes income from technical support services for 1997 and revenue generated from on going operations from 1998 through 2001.

(2) See Note 2 of the Notes to the Consolidated Financial Statements for information concerning the calculation of net loss per common share.

(3) See Note 8 of the Notes to the Consolidated Financial Statements for information concerning the accretion and dividends of the redeemable, convertible preferred stock.

(4) 1997 and 1998 include a $5,000,000 demand note payable by Safeguard Scientific, Inc., which was paid in full in June 1999. Short-term investments for 1997, 1998 and 1999 are approximately $2.4 million, $3.5 million and $5.8 million, respectively.

(5) 2001 includes convertible, redeemable preferred stock.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Overview

We develop, manufacture and market the ACIS® automated cellular imaging system, which is designed to substantially improve the accuracy, sensitivity, and reproducibility of cell imaging. Unlike manual methods of viewing and analysis, the ACIS combines proprietary, color-based imaging technology with automated microscopy to assist the pathologist in making critical medical decisions. In July 1999, the FDA granted clearance for use of the ACIS system to assist the pathologist to detect, count and classify cells of clinical interest based on recognition of cellular objects of particular color, size, and shape.

From the inception of our business on April 1, 1993 to September 30, 1999, our business was considered to be in the development stage as defined by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises". In the fourth quarter of 1999, we exited the development stage as significant revenue was realized from planned operations.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the dates of the balance sheets and revenues and expenses for the periods presented. Therefore, on an ongoing basis, we evaluate our estimates, including those provisions for bad debts, reserves for ACIS systems and ACIS in progress, valuation of the conversion feature of the Series D Convertible Preferred Stock and valuation of the related warrants and other obligations. For estimated bad debts, we review on an individual account basis the age of the receivable, all circumstances surrounding the transaction that gave rise to the receivable and whether the customer continues to have the financial resources to pay the receivable as of the balance sheet date and prior to the issuance of the financial statements for the respective period. For ACIS systems and ACIS in progress, the respective reserve is based upon the repair history of the components, the expected future use of the ACIS components based upon proposed design changes, high value components that may be discontinued in the near future and whether there are any lower of cost or market considerations. For other obligations, where judgment is required, we review the circumstances surrounding the obligation and evaluate the facts and circumstances to determine an appropriate level of accrual for such obligation.

We place most of our instruments with users on a "fee-per-use" basis. We obtain the billing information via modem, which accesses the ACIS database. Revenue is recognized based on the greater of actual usage fees or the minimum monthly rental fee. Under this pricing model, we will own most of the ACIS instruments that are engaged in service and, accordingly, all related depreciation and maintenance costs are expensed as incurred. For those instruments that are sold, we have adopted Statement of Position 97-2 (SOP 97-2), "Software Revenue Recognition," which requires that revenue from software arrangements be allocated to each element of the arrangement based on the relative fair values of the elements, such as software products, upgrades, enhancements, post contract customer support and installation. Revenue on system sales is recognized upon acceptance by the customer subsequent to a testing and evaluation period. Certain sales require continuing service, support and performance by us, and accordingly a portion of the revenue is deferred and recognized over the future service, support and performance period.

Some instruments are placed through distributors in Europe who are paid commissions based on a percentage of fees paid for use of the system as the fees accrue or as the sales take place.

Year Ended December 31, 2001 Compared with Year Ended December 31, 2000

Revenue and Gross Margin Percentage. Revenue increased approximately $3.7 million or 309% over the comparable period in 2000 due to an increase in ACIS placements, an increase in usage of the ACIS and an increase in ACIS system sales. The number of accounts in the field generating fee-per-use charges increased from 21 to 99, and average monthly revenue for our full ACIS accounts increased from $5,200 to approximately $6,000 per month over the comparable period in 2000. System sales contributed 25% of total revenue for 2001 as compared to 37% for the comparable period in 2000. Our business plan focuses on placing the ACIS under a lease arrangement in which the customer is charged based on the number of tests performed, subject to a minimum monthly payment.

However, occasional sales of the ACIS system are made to strategic research institutions. Additionally, we also sell or lease the system on a fixed rent basis in the European Community where the fee-per-use strategy is not accepted in the healthcare structure. A total of nine systems were sold in 2001 of which four were sold in Europe. The number of systems sold can fluctuate significantly principally because our focus is in the clinical market. A total of four systems were sold in 2000 of which three were sold in Europe. The gross margin percentage increased to 79% as compared to 70% in the same period in 2000 primarily due to increased revenue per ACIS placement and a reduction in the cost of the ACIS instrumentation.

Selling, general and administrative expenses. Expenses increased approximately $1.5 million or 16% over the comparable period in 2000. The increase is primarily due to an increase in staffing costs for both administrative and sales and marketing positions as the company continues ramping up for commercial activities. We anticipate selling, general and administrative expenses for 2002 to remain comparable to 2001 due to a reduction in administrative and facilities costs which will be offset by an increase in sales and marketing costs to support additional ACIS placements.

Research and development expenses. Expenses decreased approximately $40,000 or 1% over the comparable period in 2000. We anticipate that research and development expenses for 2002 will be consistent with 2001 as we have achieved an appropriate level of personnel to support the development of new system capabilities and the continuation of technological advances to the ACIS.

Other income (expense). Other income for the year ended December 31, 2001 decreased approximately $446,000 or 59% over the comparable period in 2000 due to a decrease in interest rates and a lower cash balance for 2001. The lower cash balance is due to funding of operations.

Year Ended December 31, 2000 Compared with Year Ended December 31, 1999

Revenue. Revenue increased approximately $927,000 or 345% over the comparable period in 1999 primarily due to an increase in fee-per-use charges for the ACIS and sales of the ACIS to research facilities. System sales contributed 48% and 37% to total revenue in 1999 and 2000, respectively.

Selling, general and administrative expenses. Expenses increased approximately $3.3 million or 53% over the comparable period in 1999. The increase is primarily due to increases in our sales and marketing costs related to increased staffing and continuation of our commercial launch activities for the ACIS, which began in 1999 in both the European and U.S. markets.

Research and development expenses. Expenses increased approximately $822,000 or 14% over the comparable period in 1999. The increase is primarily attributable to the addition of technical personnel to further develop and release our menu of applications.

Other income (expense). Other income for the year ended December 31, 2000 increased approximately $201,000 or 36% over the comparable period in 1999 due to an increase in interest earned on our cash balance for 2000. The increase is attributable to the investment of $18.5 million of net proceeds received from a private placement of 1,775,000 newly issued shares of common stock in October 1999 as well as the investment of $6.7 million of net proceeds received from a private placement of 560,693 newly issued shares of common stock in September 2000.

Uncertainties as to Future Operations

The year 2000 was our first full year of commercial activity in which we focused primarily on marketing and sales of the ACIS system as our menu of capabilities performed with the ACIS expanded and gained commercial acceptance. We still face significant uncertainties including those discussed below under "Liquidity and Capital Resources," our ability to achieve market acceptance of the ACIS, to manufacture the system in commercial quantities and to continue to achieve satisfactory customer reimbursement from third-party payers for tests performed using the ACIS. We also face uncertainties with respect to our ability to complete development of additional tests for the ACIS. In order to mitigate the risk that any one test will not be successfully developed, we maintain a pipeline of tests in a prioritized queue so that if any one test is not successfully developed, or market feedback suggests that a test should be given a lower priority, we can align development efforts according to priority.

Other uncertainties affecting our business include our ability to collaborate successfully with other companies, universities and research centers to develop, initiate and complete clinical trials of new applications for the ACIS and obtain governmental

approvals for the applications. Lack of success in these efforts could have a material adverse effect on the future results of our operation and our ability to generate sufficient cash flow to fund operations. In November 2000, we received a warning letter from FDA's Center for Devices and Radiological Health (CDRH) which took issue with certain claims being made for our ACIS device. The letter questioned the basis for certain claims and whether certain uses of the device exceeded the scope of FDA's clearance of ACIS. In May 2001, we resolved those issues through a series of communications with the FDA without penalty. As a result of this resolution, we continue to market our product to physicians to detect, count and classify cells of clinical interest based on recognition of color, size and shape.

Liquidity and Capital Resources

In September 2000, we completed the private placement of 560,693 shares of common stock at a price of $12.48 per share and warrants to purchase 56,070 additional shares of our common stock to a wholly owned subsidiary of Safeguard Scientifics, Inc., our largest stockholder, and VennWorks LLC, another stockholder. The warrants have a term of five years and are exercisable at the same $12.48 per share price. The net proceeds from the sale of the shares were approximately $6.7 million. In January 2001, we entered into a financing agreement with VennWorks providing for VennWorks to invest up to $5 million in our common stock at various dates and in amounts selected by us from March 30, 2001 through December 28, 2001 (subject to certain limitations). The price per share is based upon the average closing price of our common stock on the Nasdaq National Market during a 20-day trading period prior to our request to purchase, subject to a minimum of $7 per share and a maximum of $14 per share. VennWorks invested $400,000 at a per share price of approximately $7 per share pursuant to this arrangement but missed other payments due to us. As a result we accelerated the date when the entire balance of the shares were to be purchased. VennWorks failed to complete the purchase and has advised us that it does not have the funds to do so.

In July 2001, we obtained $12.5 million in additional funding through a private placement of redeemable, convertible preferred stock and warrants. Halifax Fund LP served as the lead investor in the private placement. Other investors included Safeguard Scientifics, Inc. See Note 8 to the Notes to the Condensed Consolidated Financial Statement for additional information concerning the private placement.

We have an agreement with a bank for a $5 million revolving line of credit expiring on May 30, 2002. The interest rate is prime less 0.25% or LIBOR plus 1.75% at our option. Currently, there are no borrowings outstanding under the line of credit. Any borrowings outstanding under the line of credit in the future will be collateralized by our investment in securities held by the bank having a market value equal to 111% of the principal balance of the loans. We do not intend to extend the revolving line of credit. At December 31, 2001 we had approximately $7.4 million of cash and cash equivalents, working capital of approximately $5.4 million and no long-term debt. Our ability to expand our business and fully take advantage of the opportunities available to us, particularly in our sales and marketing efforts, is currently limited by our level of cash resources. We are also obligated to redeem our outstanding Series D Convertible Preferred Stock for $12,500,000 plus any accrued and unpaid dividends in July 2004 unless the preferred shares are converted into common shares. Any such redemption is likely to require additional financing. We are currently in negotiations to acquire financing secured by our either our accounts receivable, ACIS instruments or both. In addition, Safeguard Scientifics, Inc. has indicated its present intention to support ChromaVision, as needed, under mutually acceptable terms, until at least December 31, 2002. We cannot assure you that any such support in the form of additional financing will be made available to ChromaVision by Safeguard or that the terms of any such financing will be favorable or acceptable to ChromaVision.

Capital expenditures for the twelve months ended December 31, 2001 were approximately $3million and related primarily to the manufacture of the ACIS systems placed with customers. Capital expenditures are expected to total approximately $4 million in 2002 and are expected to be primarily related to the manufacture of the ACIS for placements with customers, although our present plans could change and this amount could be materially different. Our business plan anticipates placing these instruments with users and charging a "fee-per-use" for each use of the instrument. The manufacture of these instruments will require a significant outlay of cash for which revenues will be recognized over the lease term. We anticipate that existing cash resources and additional asset based financing will be sufficient to satisfy our operating cash needs for 2002. We expect losses from operations and increases in working capital requirements will continue through most of 2002. However, we expect our operating losses in 2002 to significantly decrease due to additional ACIS placements. To support our future cash needs, we may seek additional debt or equity financing. However there can be no assurance that any such financing will be available when needed or on terms attractive to us. If we are unable to obtain sufficient additional funds, we may have to delay, scale back or eliminate some or all of our development activities, clinical studies and/or regulatory activities or cease operations entirely. Any such new financing could result in a reduction of the Series D Convertible Preferred Stock under the applicable anti-dilution provisions, a reduction in the exercise price of the related warrants, a corresponding increase in the number of shares issuable upon any such conversion or exercise and dilution to other stockholders.

We have no off-balance sheet arrangements that provide financing, liquidity or market or credit risk support or involve leasing, hedging, research and development services for our business or other similar arrangements that may expose us to liability that is not expressly reflected in the financial statements, except for the facilities and automobile lease described in Note 7 to our consolidated financial statements.

At December 31, 2000 and 2001, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

New Accounting Standards Not Yet Adopted

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations and No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. SFAS No. 141 also specifies criteria that intangible assets acquired in a purchase method business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. SFAS No. 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 will also require that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. We were required to adopt the provisions of SFAS No. 141 immediately and SFAS No. 142 effective January 1, 2002. Furthermore, any goodwill and any intangible asset determined to have an indefinite useful life that is acquired in a purchase business combination completed after June 30, 2001 will not be amortized, but will continue to be evaluated for impairment in accordance with the appropriate pre-SFAS No. 142 accounting literature. The implementation of SFAS No. 141 and SFAS No. 142 will not have a material effect on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes both SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations--Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions (Opinion 30), for the disposal of a segment of a business (as previously defined in that Opinion). SFAS No. 144 retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with SFAS No. 121. For example, SFAS No. 144 provides guidance on how a long-lived asset that is used as part of a group should be evaluated for impairment, establishes criteria for when a long-lived asset is held for sale, and prescribes the accounting for a long-lived asset that will be disposed of other than by sale. SFAS No. 144 retains the basic provisions of Opinion 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, Goodwill and Other Intangible Assets.

We are required and plan to adopt SFAS No. 144 in the quarter ending March 31, 2002. We do not expect the adoption of SFAS No. 144 for long-lived assets held for use to have a material impact on our financial statements because the impairment assessment under SFAS No. 144 is largely unchanged from SFAS No. 121. The provisions of the Statement for assets held for sale or other disposal generally are required to be applied prospectively after the adoption date to newly initiated disposal activities. Therefore, we cannot determine the potential effects that adoption of SFAS No. 144 will have on our financial statements.

Item 7a. Quantitative and Qualitative Disclosures About Market Risk.

Historically, we invested excess cash in short-term debt securities that are intended to be held to maturity. These short-term investments typically have various maturity dates, which do not exceed one year. We had no short-term investments as of December 31, 2001.

Two of the main risks associated with these investments are interest rate risk and credit risk. Typically, when interest rates rise, there is a corresponding decline in the market value of debt securities. Fluctuations in interest rates would not have a material

effect on our financial statements because of the short-term nature of the securities in which we invest and our intention to hold the securities to maturity. Credit risk refers to the possibility that the issuer of the debt securities will not be able to make principal and interest payments. We have limited the investments to investment grade or comparable securities and have not experienced any losses on our investments to date due to credit risk.

Changes in foreign exchange rates, and in particular a strengthening of the U.S. dollar, may negatively affect our consolidated sales and gross margins as expressed in U.S. dollars. To date, we have not entered into any foreign exchange contracts to hedge our exposure to foreign exchange rate fluctuations. However, as our international operations grow, we may enter into such arrangements in the future. During 2001, our foreign sales were generally denominated in four different currencies. Effective January 1, 2002, our foreign sales will be denominated in Euros. Foreign currency denominated sales have not been significant.

Item 8. Financial Statements and Supplementary Data

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
ChromaVision Medical Systems, Inc.:

We have audited the accompanying consolidated balance sheets of ChromaVision Medical Systems, Inc. and subsidiaries as of December 31, 2000 and 2001 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ChromaVision Medical Systems, Inc., and subsidiaries as of December 31, 2000 and 2001 and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America.

KPMG LLP

Orange County, California
January 25, 2002

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

ASSETS

	December 31, 2000	December 31, 2001
Current assets:		
Cash and cash equivalents	$ 9,797,698	$ 7,401,078
Accounts receivable, net	262,910	1,738,497
Other	153,522	157,071
Total current assets	10,214,130	9,296,646
Property and equipment, net	4,453,881	5,251,149
Other	233,535	517,426
Total assets	$ 14,901,546	$ 15,065,221

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 352,447	$ 832,439
Accrued payroll	628,895	759,012
Accrued liabilities	708,817	1,349,495
Investment banking fee payable	—	1,000,000
Total current liabilities	1,690,159	3,940,946
Commitments and contingencies		
Series D redeemable convertible preferred stock, $1,000 par value, authorized 12,500 shares, issued and outstanding none in 2000 and 12,500 in 2001	—	8,567,371
Stockholders' equity:		
Series C convertible preferred stock, $.01 par value, authorized 200,000 shares, none issued and outstanding	—	—
Common stock $.01 par value, authorized 50,000,000 shares, issued and outstanding 20,092,466 in 2000 and 20,188,425 in 2001	200,925	201,884
Additional paid-in capital	62,648,492	66,631,637
Accumulated deficit	(49,541,578)	(64,188,809)
Accumulated other comprehensive loss	(96,452)	(87,808)
Total stockholders' equity	13,211,387	2,556,904
Total liabilities and stockholders' equity	$ 14,901,546	$ 15,065,221

See accompanying notes to consolidated financial statements.

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,		
	1999	2000	2001
Revenue:			
Fee-per-use	$ 138,720	$ 752,101	$ 3,643,446
System sales	130,000	444,052	1,242,906
Total revenue	268,720	1,196,153	4,886,352
Cost of revenue	126,507	355,714	1,030,825
Gross profit	142,213	840,439	3,855,527
Operating expenses:			
Selling, general and administrative	6,186,332	9,453,810	10,951,564
Research and development	6,075,835	6,897,377	6,857,627
Total operating expenses	12,262,167	16,351,187	17,809,191
Loss from operations	(12,119,954)	(15,510,748)	(13,953,664)
Other income	559,124	759,872	314,114
Loss before income taxes	(11,560,830)	(14,750,876)	(13,639,550)
Income taxes	—	1,600	1,600
Net loss	(11,560,830)	$ (14,752,476)	$ (13,641,150)
Accretion of and dividends on redeemable, convertible preferred stock	—	—	(1,006,081)
Net loss attributable to common stock	$ (11,560,830)	$ (14,752,476)	$ (14,647,231)
Basic and diluted net loss per common share	$ (.64)	$ (.75)	$ (.73)
Weighted average number of common shares outstanding	18,027,471	19,656,421	20,150,279

See accompanying notes to consolidated financial statements.

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total	Comprehensive Loss
Balances at December 31, 1998	17,270,816	172,708	36,442,784	(23,228,272)	—	13,387,220	
Exercise of stock options	442,813	4,428	726,960	—	—	731,388	
Sale of common stock	1,775,000	17,750	19,951,000	—	—	19,968,750	
Offering costs	—	—	(1,377,840)	—	—	(1,377,840)	
Comprehensive loss:							
Net loss	—	—		(11,560,830)	—	(11,560,830)	(11,560,830)
Foreign currency translation adjustment	—	—	—	—	(28,630)	(28,630)	(28,630)
Comprehensive loss	—	—	—	—	—	—	(11,589,460)
Balances at December 31, 1999	19,488,629	194,886	55,742,904	(34,789,102)	(28,630)	21,120,058	
Exercise of stock options	43,144	431	309,522	—	—	309,953	
Sale of common stock	560,693	5,608	6,994,392	—	—	7,000,000	
Offering costs	—	—	(398,326)	—	—	(398,326)	
Comprehensive Loss:							
Net loss	—	—	—	(14,752,476)	—	(14,752,476)	(14,752,476)
Foreign currency translation adjustment	—	—	—	—	(67,822)	(67,822)	(67,822)
Comprehensive loss	—	—	—	—	—	—	$(14,820,298)
Balances at December 31, 2000	20,092,466	200,925	62,648,492	(49,541,578)	(96,452)	13,211,387	
Exercise of stock options	20,837	208	117,421	—	—	117,629	
Purchase of stock under ESPP	18,165	182	46,640	—	—	46,822	
Redeemable preferred stock beneficial conversion	—	—	1,148,421	—	—	1,148,421	
Common stock warrants	—	—	2,295,162	—	—	2,295,162	
Accretion of redeemable preferred stock	—	—		(707,472)	—	(707,472)	
Preferred dividends payable	—	—		(298,609)	—	(298,609)	
Sale of common stock	56,957	569	399,431	—	—	400,000	
Common stock offering costs	—	—	(23,930)	—	—	(23,930)	
Comprehensive Loss:							
Net loss	—	—		(13,641,150)		(13,641,150)	(13,641,150)
Foreign currency translation adjustment	—	—	—	—	8,644	8,644	8,644
Comprehensive loss	—	—	—	—	—	—	$(13,632,506)
Balances at December 31, 2001	20,188,425	$201,884	$66,631,637	$(64,188,809	$(87,808)	$2,556,904	

See accompanying notes to consolidated financial statements

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,		
	1999	2000	2001
Cash flows from operating activities:			
Net loss	$ (11,560,830)	$ (14,752,476)	$ (13,641,150)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,430,527	1,920,012	2,158,087
Changes in operating assets and Liabilities:			
Accounts receivable	(22,519)	(238,202)	(1,479,332)
Other	(92,065)	51,501	(288,260)
Accounts payable	113,534	(225,816)	480,971
Accrued payroll	15,058	303,776	130,864
Accrued liabilities	(51,677)	302,217	346,887
Net cash used in operating activities	(10,167,972)	(12,638,988)	(12,291,933)
Cash flows from investing activities:			
Note receivable - affiliate	5,000,000	—	—
Purchases of investments	(5,822,451)	—	—
Maturities of investments	3,533,747	5,822,451	—
Purchases of property and equipment	(2,883,947)	(2,029,208)	(2,955,355)
Net cash (used in) provided by investing activities	(172,651)	3,793,243	(2,955,355)
Cash flows from financing activities:			
Proceeds from exercise of stock options and issuance of stock under employee stock purchase plan	731,388	309,953	164,451
Sale of convertible preferred stock	—	—	12,500,000
Issuance costs on sale of convertible preferred stock	—	—	(196,517)
Sale of common stock	19,968,750	7,000,000	400,000
Common stock offering costs	(1,377,840)	(398,326)	(23,930)
Net cash provided by financing activities	19,322,298	6,911,627	12,844,004
Effect of exchange rate changes on cash and cash equivalents	(32,553)	(70,852)	6,664
Net increase (decrease) in cash and cash equivalents	8,949,122	(2,004,970)	(2,396,620)
Cash and cash equivalents beginning of year	2,853,546	11,802,668	9,797,698
Cash and cash equivalents end of year	$ 11,802,668	$ 9,797,698	$ 7,401,078
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ —	$ —
Cash paid for income taxes	$ —	$ 3,978	$ 1,600
Non-cash investing and financing activities:			
Issuance of warrants relating to the preferred stock financing	$ —	$ —	$ 2,295,162
Beneficial conversion feature relating to the preferred stock financing	$ —	$ —	$ 1,148,421
Accretion of preferred stock dividend	$ —	$ —	$ 298,609
Investment banking fee paid in January 2002	$ —	$ —	$ 1,000,000
Accretion of preferred stock	$ —	$ —	$ 707,472

See accompanying notes to consolidated financial statements.

CHROMAVISION MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Organization

Overview

We develop, manufacture and market the ACIS® automated cellular imaging system, which is designed to substantially improve the accuracy, sensitivity, and reproducibility of cell imaging. Unlike manual methods of viewing and analysis, the ACIS combines proprietary, color-based imaging technology with automated microscopy to assist the pathologist in making critical medical decisions. In July 1999, the FDA granted clearance for use of the ACIS system to assist the pathologist to detect, count and classify cells of clinical interest based on recognition of cellular objects of particular color, size, and shape.

(2) Summary of Significant Accounting Policies

(a) Basis of Consolidation

The consolidated financial statements include the results of operations, account balances and cash flows of the Company and our wholly owned subsidiaries. All significant inter-company accounts and transactions have been eliminated in consolidation.

(b) Change in Development Stage Status

From the inception of the business on April 1, 1993 to September 30, 1999, we were considered to be in the development stage as defined by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises". In the fourth quarter of 1999, we exited the development stage as significant revenue was realized from planned operations.

(c) Revenue Recognition

We place most of our instruments with users on a "fee-per-use" basis. We obtain the billing information via modem, which accesses the ACIS database. Revenue is recognized based on the greater of actual usage fees or the minimum monthly rental fee. Under this pricing model, we will own most of the ACIS instruments that are engaged in service and, accordingly, all related depreciation and maintenance costs are expensed as incurred. For those instruments that are sold, we have adopted Statement of Position 97-2 (SOP 97-2), "Software Revenue Recognition," which requires that revenue from software arrangements be allocated to each element of the arrangement based on the relative fair values of the elements, such as software products, upgrades, enhancements, post contract customer support and installation. Revenue on product sales is recognized upon acceptance by the customer subsequent to a testing and evaluation period. Certain sales require continuing service, support and performance by us, and accordingly a portion of the revenue is deferred and recognized over the future service, support and performance period.

Some instruments are placed through distributors in Europe who are paid commissions based on a percentage of fees paid for use of the system as the fees accrue or as the sales take place.

(d) Cash and Cash Equivalents

Cash and cash equivalents consist of amounts held as bank deposits and highly liquid debt instruments with a maturity of three months or less. No single investment exceeded 5% of the combined total of cash and cash equivalents at December 31, 2000 and 2001.

We have not experienced any significant losses on cash equivalents and do not believe we are exposed to any significant credit risk on such cash equivalents.

(e) Depreciation and Amortization

Property and equipment are depreciated and amortized on the straight-line basis over the following estimated useful lives:

Office, Computer and Laboratory Equipment	3 to 5 years
Automated Cellular Imaging Systems (ACIS)	3 years
Furniture and Fixtures	5 years
Leasehold Improvements	Life of lease

Expenditures for maintenance, repairs and minor improvements are charged to expense as incurred. Major improvements and additions are capitalized. ACIS instruments begin depreciation upon placement, at which time depreciation related to ACIS instruments placed for research and development or placed for commercial use are expensed in research and development or cost of sales, respectively.

The following is a summary of property and equipment:

	December 31,	
	2000	2001
Office, computer and laboratory equipment	$ 1,215,868	$ 1,741,990
Automated Cellular Imaging Systems (ACIS)	5,292,636	7,340,001
ACIS in progress	662,974	834,696
Furniture and fixtures	543,034	588,722
Leasehold improvements	605,029	769,128
	$ 8,319,541	$ 11,274,537
Less: accumulated depreciation	3,865,660	6,023,388
Property and equipment, net	$ 4,453,881	$ 5,251,149

Long-lived assets are reviewed for impairment utilizing undiscounted estimated future cash flows from the use of the assets whenever events or changes in circumstances indicate the carrying amount may not be recoverable. If the fair value, based on the present value of estimated future cash flows, is less than the carrying amount of the assets, a loss is recognized for the difference.

(f) Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

(g) Stock-Based Compensation

We apply Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), for stock options and other stock-based awards to employees while disclosing pro forma net loss and net loss per share as if the fair value method had been applied in accordance with Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS No.123), see Note 4. The fair value of options granted to non-employees is expensed over the performance period or at the time when a performance commitment is reached.

(h) Net Loss Per Share

Basic and diluted loss per common share is calculated by dividing net loss by the weighted average common shares outstanding during the year. Stock options and warrants to purchase 2,121,675, 2,642,076, and 3,818,810 shares of common stock were outstanding at December 31, 1999, 2000 and 2001, respectively. These stock options and warrants outstanding were not included in the computation of diluted earnings per share because we incurred a loss in all periods presented and hence, the impact would be

anti-dilutive. For the period ended December 31, 2001, dilutive potential common shares of approximately 1,901,256 consisting of convertible preferred stock have also been excluded from the computation of diluted income per share as their effect is anti-dilutive.

(i) Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. Actual results could differ from those estimates. Significant estimates include the depreciation and valuation of ACIS systems and ACIS in progress and receivables valuations as well as valuation of the stock warrants and the beneficial conversion feature of the convertible, redeemable preferred stock.

(j) Financial Instruments

We estimate the fair value of our monetary assets and liabilities based upon the existing interest rates related to such assets and liabilities compared to current market rates of interest for instruments with a similar nature and degree of risk. We estimate that the fair value of all of our monetary assets and liabilities approximates the recorded value as of December 31, 2000 and 2001.

(k) Accounts Receivable

Our customer base is comprised of two principal market segments, 1) the clinical market which consists of hospitals, pathology practice groups and reference laboratories and 2) the research and biotechnology market which consists of pharmaceutical companies, universities and research institutions. Our customer base is geographically diverse and historically we have not experienced significant losses related to receivables for our fee-per-use revenue. We periodically perform credit evaluations on our customers and we do not require collateral. The majority of our customers are billed monthly based on their fee-per-use activity. We estimate an allowance for doubtful accounts based upon the actual payment history of each customer in addition to reserving for a portion of receivables that are delinquent. Accounts receivable is net of a reserve for doubtful accounts at December 31, 2000 and 2001, of $130,000 and $287,000, respectively.

We are not materially dependent on any individual customer. Our largest customer, excluding ACIS system sales, approximated 9% or $110,000 and 10% or $474,000 of total revenue for December 31, 2000 and 2001, respectively. When a sale of one of our systems is made, the sale price is large in relation to the income flow from leasing for a single year. However, ACIS sales are made only occasionally, ChromaVision has never sold more than one system to a customer, and ChromaVision believes that it is not dependent upon any past sale customer for future revenue.

(l) Recent Accounting Developments

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations and No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. SFAS No. 141 also specifies criteria that intangible assets acquired in a purchase method business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. SFAS No. 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 will also require that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. We were required to adopt the provisions of SFAS No. 141 immediately and SFAS No. 142 effective January 1, 2002. Furthermore, any goodwill and any intangible asset determined to have an indefinite useful life that is acquired in a purchase business combination completed after June 30, 2001 will not be amortized, but will continue to be evaluated for impairment in accordance with the appropriate pre-SFAS No. 142 accounting literature. The implementation of SFAS No. 141 and SFAS No. 142 will not have a material effect on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes both SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations--Reporting the Effects of

Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions (Opinion 30), for the disposal of a segment of a business (as previously defined in that Opinion). SFAS No. 144 retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with SFAS No. 121. For example, SFAS No. 144 provides guidance on how a long-lived asset that is used as part of a group should be evaluated for impairment, establishes criteria for when a long-lived asset is held for sale, and prescribes the accounting for a long-lived asset that will be disposed of other than by sale. SFAS No. 144 retains the basic provisions of Opinion 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, Goodwill and Other Intangible Assets.

We are required and plan to adopt SFAS No. 144 in the quarter ending March 31, 2002. We do not expect the adoption of SFAS No. 144 for long-lived assets held for use to have a material impact on our financial statements because the impairment assessment under SFAS No. 144 is largely unchanged from SFAS No. 121. The provisions of the Statement for assets held for sale or other disposal generally are required to be applied prospectively after the adoption date to newly initiated disposal activities. Therefore, we cannot determine the potential effects that adoption of SFAS No. 144 will have on our financial statements

(m) Foreign Currency Translation

The financial position and results of operations of our foreign subsidiaries are generally determined using their local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each year-end. Statement of operations accounts are translated at the average rate of exchange prevailing during the year. Translation adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive loss in stockholders' equity. Foreign currency translation (losses) and gains were $(28,630), $(67,822) and $8,644 for the years ending December 31, 1999, 2000 and 2001.

Foreign currency transaction gains or losses were not material in any of the periods presented.

(3) Line of Credit

We have an agreement with our principal bank for a $5,000,000 revolving line of credit. The line expires on May 30, 2002 and we do not intend to extend or renew the revolving line of credit. At our option, the interest rate is either prime less 0.25% or LIBOR plus 1.75%. There were no borrowings outstanding under the line of credit during the period. Any borrowings outstanding under the line of credit will be collateralized by our investment in securities held by the principal bank having a market value equal to 111% of the principal balance of the loans.

(4) Stock Options

We have a stock option plan (the "Plan") pursuant to which our Board of Directors or a committee of the Board may grant stock options to employees, directors and consultants. The Plan authorizes grants of options to purchase up to 3,700,000 shares of authorized but unissued common stock. All options granted by us had an exercise price equal to the stock's fair value at the date of grant. Stock options granted have terms of up to ten years and become exercisable in increments over periods of up to four years.

We granted non-qualified stock options in 1999, 2000 and 2001 to purchase 30,000 shares, 61,000 shares, and 35,500 shares respectively, to consultants of ChromaVision at prices between $3.19 and $5.31 per share. We recorded compensation expense of approximately, $50,000, $75,000, and $58,000 for the years ended December 31, 1999, 2000 and 2001 respectively, related to these consultant options. At December 31, 2001, consultant options to purchase approximately 213,000 shares were exercisable.

Option activity is summarized as follows:

	1999		2000		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,050,938	$ 3.27	2,121,675	$ 5.29	2,586,006	$ 6.59
Options granted	554,550	9.63	558,175	11.69	786,856	4.19
Options exercised	(442,813)	1.41	(43,144)	5.42	(20,837)	2.87
Options canceled	(41,000)	5.06	(50,700)	9.20	(135,900)	7.06
Outstanding at end of year	2,121,675	$ 5.29	2,586,006	$ 6.59	3,216,125	$ 6.01
Options exercisable at year-end	1,130,799		1,474,042		1,877,073	
Shares available for future grant	933,138		425,663		274,707	

The following summarizes information about our stock options outstanding at December 31, 2001:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at 12/31/01	Weighted Avg. Remaining Contractual Life (in years)	Weighted Avg. Exercise Price	Number Exercisable at 12/31/01	Weighted Avg. Exercise Price
At $ 0.80	12,500	1.45	$ 0.80	12,500	$ 0.80
$ 2.38 — $ 2.40	923,194	4.52	$ 2.40	905,570	$ 2.40
$ 2.63 — $ 4.19	340,250	6.57	$ 3.45	21,500	$ 3.42
$ 4.20 — $ 4.35	381,250	6.25	$ 4.32	46,250	$ 4.25
$ 4.44 — $ 5.31	328,556	5.92	$ 5.04	133,125	$ 5.00
$ 5.56 — $ 6.00	398,900	6.28	$ 5.74	322,275	$ 5.75
$ 6.25 — $ 9.25	352,500	7.24	$ 8.29	209,201	$ 8.16
$ 9.31 — $ 13.50	323,950	7.04	$ 12.21	141,076	$ 12.35
$ 13.63 — $ 15.63	17,900	8.15	$ 15.02	4,475	$ 15.02
At — $ 23.19	137,125	8.12	$ 23.19	81,101	$ 23.19
$ 0.80 — $ 23.19	3,216,125	6.02	$ 6.01	1,877,073	$ 5.52

We apply APB 25 and related interpretations in accounting for stock option plans. Had compensation cost been recognized consistent with SFAS No. 123, our consolidated net loss and loss per share would have been increased to the pro forma amounts indicated below:

		1999	2000	2001
Consolidated net loss attributable to common stock	As reported	$(11,560,830)	$(14,752,476)	$(14,647,231)
	Pro forma	$(12,894,567)	$ (17,787,376)	$(17,301,128)
Loss per share — Basic and Diluted	As reported	$ (.64)	$ (.75)	$ (.73)
	Pro forma	$ (.72)	$ (.90)	$ (.86)

The per share weighted-average fair value of stock options granted by us during 1999, 2000 and 2001 was $6.26, $7.88 and $3.29, respectively, on the date of grant.

The following assumptions were used by us to determine the fair value of stock options granted using the Black-Scholes option-pricing model:

	1999	2000	2001
Dividend yield	0.0%	0.0%	0.0%
Volatility	85.0%	90.0%	118.4%
Average expected option life	4 years	4 years	4 years
Risk-free interest rate	5.2 – 6.4%	5.0 – 6.5%	3.9 – 5.0%

(5) Income Taxes

The following table summarizes the tax effects of temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards which give rise to significant portions of the deferred tax assets and liability at December 31:

	1999	2000	2001
Deferred tax assets:			
Current assets:			
Accrued liabilities and other deferred tax assets	$ 358,161	$ 446,729	$ 517,404
Non-current assets:			
Net operating loss carryforward	11,635,241	17,652,801	21,877,597
Intangible asset, net of amortization	1,425,563	1,301,461	1,072,659
Depreciation	44,605	160,706	198,447
Accrued liabilities and other deferred tax assets	51,330	497,911	804,198
Federal tax credit carryover	434,576	1,351,309	2,463,713
Non-current deferred tax assets	13,591,315	20,964,188	26,416,614
Total	13,949,476	21,410,917	26,934,018
Less valuation allowance for net deferred tax assets	(13,949,476)	(21,410,917)	(26,934,018)
Deferred tax assets (liability), net	$ -0-	$ -0-	$ -0-

The valuation allowance increased by $5,523,101 for the year ended December 31, 2001. Recognized tax benefits relating to the valuation allowance for deferred tax assets as of December 31, 2001 are allowed as follows:

Income tax benefit resulting from operations	$ 25,928,032
Additional paid-in capital	1,005,986
Total valuation allowance	$ 26,934,018

Actual income tax expense differs from amounts computed by applying the U.S. federal income tax rate of 34% to pretax loss as a result of the following for the year ending December 31:

	1999	2000	2001
Computed expected tax benefit	$ (3,936,170)	$ (5,015,842)	$ (4,637,447)
State income taxes net of federal benefit	(746,823)	(784,687)	(545,646)
Nondeductible expenses	73,601	58,611	38,264
Change in valuation allowance	4,707,669	6,474,835	5,523,101
Tax credit benefit	(152,328)	(704,213)	(411,403)
Other	54,051	(27,104)	34,731
Actual tax expense	$ —	$ 1,600	$ 1,600

As of December 31, 2001, we have net operating loss carryforwards for federal and state income tax purposes of approximately $59,184,000 and $36,933,000, respectively, which will commence expiration in 2011 and 2005, respectively. As of December 31, 2001, we have tax credit carryforwards for federal and state income tax purposes of $1,547,000 and $1,390,000, respectively, which will begin to expire in 2011.

In accordance with Internal Revenue Code section 382, the annual utilization of net operating loss carryforwards and credits existing prior to a change in control in the company may be limited after a change in control.

(6) Related Party Transactions

We have historically had an administrative services agreement with Safeguard Scientifics, Inc. under which Safeguard Scientifics, Inc. provided us with administrative support services, including management consultation, investor relations, legal services and tax planning. In consideration for these services, we were obligated to pay an annual fee of 0.75% of our gross revenues each year to Safeguard Scientifics, Inc., up to a maximum of $300,000 per year in the aggregate. Fees were to accrue until we achieved a positive cash flow from operations. Effective April 1, 2000, this agreement and the obligation to make payments thereunder were mutually terminated without any payment. We had accrued charges of approximately $12,000 at the time of termination. We also

entered into the same administrative service agreement with XL Vision, Inc. During 2001, XL Vision entered into Chapter 7 bankruptcy proceedings and is currently in liquidation. Approximately $21,000 remains accrued under this agreement as of December 31, 2001

We earned $115,000 of interest income on a demand note receivable from Safeguard Scientifics, Inc. during 1999.

(7) Commitments and Contingencies

Voluntary Employee Retirement 401(k) Plan. We have a voluntary employee retirement 401(k) plan, which is available to all full time employees' 21 years or older. Through 2001, the plan provided for a matching by us of the employee's contribution to the plan for 50% of the first 6% of the employee's annual compensation. Beginning in 2002, the plan provides for a matching by us of the employee's contribution to the plan for 33.3% of the first 6% of the employee's annual compensation. Our matching contributions were approximately $116,000, $153,000, and $181,000 for the years ended December 31, 1999, 2000 and 2001, respectively.

Lease Commitment. We utilized various operating leases for office space, furniture, and an automobile. We purchased the furniture at the end of its lease in 2001. The office space and automobile leases both terminate in 2003. At that time, we expect that we will enter into a subsequent lease agreement for office space. Rental commitments under these agreements for 2002 and 2003 are approximately $157,000 and $29,000, respectively. Total rent expense related to these leases was approximately $163,000, $177,000, and $169,000 for years ended December 31, 1999, 2000, and 2001.

Regulatory. In November 2000, we received a warning letter from FDA's Center for Devices and Radiological Health (CDRH) which took issue with certain claims being made for our ACIS device. The letter questioned the basis for certain claims and whether certain uses of the device exceeded the scope of FDA's clearance of ACIS. In May 2001, we resolved those issues through a series of communications with the FDA. As a result of this resolution, we continue to market our product to physicians to detect, count and classify cells of clinical interest based on recognition of color, size and shape.

(8) Stock Transactions

In October 1999, we completed a private placement of 1,775,000 shares of common stock to selected institutional and other accredited investors. The net proceeds from the sale of the shares were approximately $18.5 million. The shares were registered for resale under the Securities Act of 1933 shortly after they were issued.

In September 2000, we completed the private placement of 560,693 shares of our common stock and warrants to purchase 56,070 additional shares of our common stock to two institutional investors for a purchase price of $7 million. The net proceeds from the sale of the shares were approximately $6.7 million. The purchase price per share was $12.48 and was based upon an average of high and low trading prices of our common stock for a 20-day period prior to the sale. The warrants have a term of five years and are exercisable at the same $12.48 per share price. Of the $7,000,000 purchase price, $5,000,000 was purchased by a wholly owned subsidiary of Safeguard Scientifics, Inc., and $2,000,000 was purchased by VennWorks LLC, a private investment fund. Safeguard Scientifics, Inc. already held approximately 27% of our outstanding shares, and VennWorks was also a stockholder. We have since registered the shares purchased and the shares issuable upon exercise of the warrants for resale under the Securities Act of 1933 under certain circumstances.

In September 2000, we amended our Stockholder Rights Plan, which had been adopted in March 1999 and was previously amended in June 1999. The Stockholder Rights Plan provides for the distribution of rights to purchase additional shares of our capital stock in the event any person, entity or group acquires beneficial ownership of 15% or more of our outstanding voting shares. The Plan included an exception for acquisitions of shares by persons, entities or groups who, as of February 10, 1999, were the beneficial owner of more than 15% of the outstanding shares of our common stock. (These beneficial owners are referred to below as "Existing 15% Owners.") That exemption in the Plan applied only if (1) an Existing 15% Owner continued to own at least 15% of our Voting Shares and (2) did not acquire additional Voting Shares which would cause the Existing 15% Owner's beneficial ownership of Voting Shares to exceed 40% of the number of shares outstanding.

This amendment to the Plan made three changes. First, it exempts from the provision described above the acquisition of 400,495 shares of common stock and warrants to purchase an additional 40,050 shares of common stock acquired by the subsidiary of Safeguard Scientifics, Inc., in the private placement described above. Second, it amends the definition of "15% Stockholder" to

exclude any Exempted Group. Third, it defines Exempted Group as any group consisting of Safeguard, its affiliates and associates, and VennWorks LLC and its affiliates and associates, but only so long as (i) Safeguard Scientifics, Inc. and its affiliates and associates beneficially own more than a majority of our voting shares beneficially owned in the aggregate by Safeguard Scientifics, Inc.; its affiliates and associates, VennWorks LLC and its affiliates and associates and (ii) Safeguard Scientifics, Inc., its affiliates and associates, and VennWorks LLC and its affiliates and associates do not beneficially own in the aggregate more than 45% of our Voting Shares then outstanding.

In January 2001, we entered into a financing agreement with VennWorks LLC providing for VennWorks to invest up to $5 million in our common stock at various dates and in amounts selected by us from March 30, 2001 through December 28, 2001 (subject to certain limitations). The price per share was based upon the average closing price of our common stock on the Nasdaq National Market during a 20-day trading period prior to our request to purchase, subject to a minimum of $7 per share and a maximum of $14 per share. VennWorks had invested $400,000 at a per share price of approximately $7 per share pursuant to this arrangement but missed other payments due to us. As a result we accelerated the date when the entire balance of the shares were to be purchased. VennWorks failed to complete the purchase and has advised us that it does not have the funds to do so.

On July 10, 2001, we obtained $12.5 million in additional funding through a private placement of redeemable, convertible preferred stock and warrants to seven institutional investors. Halifax Fund LP served as the lead investor of the private placement. Other investors included a subsidiary of Safeguard Scientifics, Inc., currently our largest shareholder.

The preferred stock bears a 5% cumulative annual dividend payable in cash or common stock and is convertible into common stock at $6.57 per share. The number of shares of common stock presently issuable upon conversion of the preferred stock is 1,901,256, but that number is subject to adjustment corresponding to adjustments in the conversion price. The preferred stock is required to be redeemed by us three years after issuance for the amount paid for the preferred stock plus accrued and unpaid dividends.

The warrants are exercisable to purchase an aggregate of 546,615 shares of common stock at any time after issuance for a period of five years at a price of $6.86 per share, which represents 120% of the market price of our common stock over a designated period prior to closing. The number of shares issuable upon exercise of the warrants is subject to adjustment corresponding to adjustments on the exercise price. The Company allocated the total amount paid by the investors, net of issuance costs, between the preferred stock, the fair market value of the warrants and the intrinsic value of the conversion feature of the preferred stock. The fair market value of the warrants was determined to be approximately $2,295,000 (using the Black Sholes valuation model). The remaining net amount paid by the investors divided by the number of shares issuable upon conversion of the preferred stock is the effective conversion price of the preferred, and the difference between the fair market value of the common stock on the date of issuance of the preferred and the effective conversion price is the intrinsic value of the conversion feature, which amounted to $1,148,421. The fair market value of the warrants and the intrinsic value of the conversion feature are allocated to paid-in-capital and are accreted (amortized) over the three year period prior to mandatory redemption of the preferred stock. The issuance costs of approximately $1,197,000 are also recorded as a discount to the preferred stock and are accreted over the three-year redemption period.

Under the terms of the transaction documents, the preferred stock is required to be converted into common stock if the trading price of the common stock equals or exceeds 175% of the initial conversion price for 20 out of 30 consecutive trading days occurring after the first anniversary of the purchase of the preferred stock. The conversion price of the preferred stock and the exercise price of the warrants are subject to adjustment upon the occurrence of certain events, including an adjustment after one year if the current average trading price of the common stock for a designated period is less than the conversion or exercise price, respectively, but the amount of the adjusted price for the one-year adjustment cannot be less than a floor of $4.0019 per share.

(9) Business Segments

We operate primarily in one business segment engaged in the development, manufacture and marketing of an automated cellular imaging system which is designed to assist physicians in making critical medical decisions.

The following table represents business segment information by geographic area:

	Year Ended December 31,		
	1999	2000	2001
Net sales			
United States	$ 188,120	$ 1,009,160	$ 4,500,786
Europe (a)	80,600	186,993	385,566
Total net sales	$ 268,720	$ 1,196,153	$ 4,886,352
Operating loss			
United States	$ 12,044,986	$ 15,429,339	$ 13,837,963
Europe (a)	74,968	81,409	115,701
Total operating loss	$ 12,119,954	$ 15,510,748	$ 13,953,664
Identifiable assets			
United States	$ 22,283,123	$ 14,767,927	$ 14,814,642
Europe (a)	151,732	133,619	250,579
Total assets	$ 22,434,855	$ 14,901,546	$ 15,065,221

(a) European operations represent business activities conducted primarily in Germany, Great Britain, Switzerland and France.

(10) Employee Stock Purchase Plan

In April 2001, the Board of Directors approved an employee stock purchase plan (the "Purchase Plan") which has a total of 1,000,000 shares reserved for issuance thereunder. All full-time employees are eligible to participate, but there are various limitations regarding the amount of shares which may be purchased. The purchase price at which shares are sold under the Purchase Plan cannot be less than 85% of the fair market value per share of our common stock at either the enrollment date or at the last day of the offering period, whichever is lower. Offerings under the Purchase Plan have a duration of three months. The first offering period began July 1, 2001. During 2001, 18,165 shares were issued at a price of $2.58.

(11) Quarterly Results of Operations (Unaudited)

Quarter Ended:	Total Revenue	Gross Profit	Net Loss	Net Loss Per Share
December 31, 2001	$ 1,746,197	$ 1,372,720	$ (2,880,139)	$ (.17)
September 30, 2001	1,242,188	985,648	(3,422,257)	(.19)
June 30, 2001	949,423	754,343	(3,699,948)	(.18)
March 31, 2001	948,544	742,816	(3,638,806)	(.18)
December 31, 2000	$ 442,854	$ 336,594	$ (3,898,335)	$ (.19)
September 30, 2000	211,581	143,164	(3,963,628)	(.20)
June 30, 2000	337,822	224,060	(3,699,457)	(.19)
March 31, 2000	203,896	136,621	(3,191,056)	(.16)

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosure***

None

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

Directors

We incorporate by reference the information contained under the caption "ELECTION OF DIRECTORS" in its definitive Proxy Statement relative to its June 5, 2002 annual meeting of shareholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Act of 1934, as amended.

Executive Officers

The information with respect to executive officers required by this Item is set forth in Part I of this report.

Item 11. ***Executive Compensation***

We incorporate by reference the information contained under the captions "Directors' Compensation," "Compensation Committee Interlocks and Insider Participation" and "EXECUTIVE COMPENSATION" in its definitive Proxy Statement relative to its June 5, 2002 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

We incorporate by reference the information contained under the caption "SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT" in its definitive Proxy Statement relative to its June 5, 2002 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

Item 13. ***Certain Relationships and Related Transactions***

We incorporate by reference the information contained under the captions "Compensation Committee Interlocks and Insider Participation," "Certain Relationships" and "Certain Transactions" in its definitive Proxy Statement relative to its June 5, 2002 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

PART IV

Item 14. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K***

(a) Financial Statements and Schedules

The following financial statements and schedules listed below are included in this Form 10-K.

Financial Statements (See Item 8)
Independent Auditors' Report
Consolidated Balance Sheets as of December 31, 2000 and 2001
Consolidated Statements of Operations for the Years Ended December 31, 1999, 2000 and 2001
Consolidated Statements of Shareholders' Equity (Deficit) for the Years Ended December 31, 1999, 2000, and 2001
Consolidated Statements of Cash Flows for the Years Ended December 31, 1999, 2000, and 2001
Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II-Valuation and Qualifying Accounts

(b) Reports on Form 8-K

We filed a Form 8-K with the Securities and Exchange Commission on March 1, 2002 to report that on February 12, 2002 the Board of Directors set the date for the 2002 Annual Meeting of Stockholders for June 5, 2002. Also at the February 12, 2002 meeting, the Board of Directors of the Company adopted amendments to its bylaws requiring advance notice of proposals for business to be conducted at annual meetings of stockholders and for nominations of directors by stockholders at stockholder meetings. These provisions will apply to the 2002 Annual Meeting. No financial statements were filed with this report.

(c) Exhibits

The following is a list of exhibits filed as part of this Form 10-K. Where so indicated by footnotes, exhibits which were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated in parentheses.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (as amended)(a)
3.2	Certificate of Designations of Series C Preferred Stock(b)
3.3	Certificate of Designations of the Powers and Preferences and Relative, Participating, Optional and Other Special Rights of Preferred Stock and Qualifications, Limitations and Restrictions Thereof of Series D 5% Cumulative Convertible Preferred Stock(c)
3.4	By-laws of the Company, as amended (a)
10.1	ChromaVision Medical Systems, Inc. 1996 Equity Compensation Plan(a)
10.2	Employment Agreement, as amended, between Dr. Douglas S. Harrington and the Company, as of January 10, 2001(d)
10.3	Employment Agreement, as amended, between Kevin C. O'Boyle and the Company, dated January 10, 2001(d)
10.4	Employment Agreement between Jose de la Torre-Bueno, Ph.D. and the Company, dated January 10, 2001(d)
10.5	Employment Agreement between Carl W. Apfelbach and the Company, dated May 4, 2001(e)
10.6	Lease Agreement between Blue Family Trust, Lingo Family Trust and the Company, dated January 13, 1997(a)

EXHIBIT INDEX (CONT.)

Exhibit Number	Description
10.7	Administrative Services Agreement among the Company, XL Vision, Inc. and Safeguard Scientifics, Inc. dated as of March 31, 1997(a)
10.8	Rights Agreement dated as of February 10, 1999 between the Company and Harris Trust Company of California, as Rights agent (b)
10.9	Amendment to rights Agreement dated June 12, 1999 between the Company and Harris Trust Company of California, as Rights Agent (g)
10.10	Amendment No. 2 to Rights Agreement dated September 18, 2000 between the Company and Harris Trust Company of California, as rights Agent (h)
10.11	Securities Purchase Agreement dated as of July 10, 2001 by and among the Company Medical systems, Inc. and the securities purchasers named therein (c)
10.12	Registration rights Agreement entered into as of July 10, 2001 by and between the Company Medical Systems, Inc and the securities purchasers named therein (c)
10.13	Form of Common Stock Purchase Warrant dated July 10, 2001 entered into by the Company Medical Systems, Inc. with each of the other parties to the Securities Purchase Agreement referred to above as Exhibit 10.11 (except that the warrant issued to Safeguard Delaware, Inc. omits Sections 18 (a) through (c)) (c)
10.14	Agreement dated February 2002 between Halifax Fund, L.P. and the Company (with schedule indicating differences between this Agreement and those nearly identical agreements entered into with each of the other parties to the Securities Purchase Agreement referred to above as Exhibit 10.11) (e)
10.15	Stock Purchase Agreement dated September 24, 2000 among the Company, Safeguard Delaware, Inc. and incuVest LLC (h)
10.16	Stock Purchase Agreement dated January 31, 2000 between the Company and incuVest LLC (d)
10.17	Amendment to Stock Purchase Agreement dated April 18, 2991 between the Company and VennWorks LLC (formerly named incuVest LLC) (i)
21.1	Subsidiaries of the Registrant(a)
23	Consent of KPMG LLP(e)

(a) Filed on April 30, 1997 as an exhibit to the Company's Registration Statement on Form S-1 (No. 333-26129) and incorporated by reference.

(b) Filed on March 12, 1999 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(c) Filed on July 12, 2001 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(d) Filed on April 2, 2001 as an exhibit to the Company's Annual Report on Form 10-K and incorporated by reference

(e) Filed herewith

(f) Filed on September 28, 1999 as an exhibit to the Company's Registration Statement on Form S-3 (No. 33387969) and incorporated by reference.

(g) Filed on July 2, 1999 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference

(h) Filed on October 10, 2000 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference

(i) Filed on May 15, 2001 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference

SIGNATURES

Pursuant to the requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned; thereunto duly authorized, in San Juan Capistrano, California on April 1, 2002.

CHROMAVISION MEDICAL SYSTEMS, INC.

By: /s/ CARL W. APFELBACH
Carl W. Apfelbach
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities indicated on April 1, 2002.

Signatures	Title(s)
/s/ CARL W. APFELBACH Carl W. Apfelbach	Chief Executive Officer, President & Director (Principal Executive Officer)
/s/ KEVIN C. O'BOYLE Kevin C. O'Boyle	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ DOUGLAS S. HARRINGTON, M.D. Douglas S. Harrington, M.D.	Chairman of the Board of Directors
/s/ MICHAEL F. COLA Michael F. Cola	Director
/s/ ERIC S. KENTOR Eric S. Kentor	Director
/s/ MARY LAKE POLAN, M.D. Mary Lake Polan, M.D.	Director
/s/ CHARLES A. ROOT Charles A. Root	Director
/s/ THOMAS R. TESTMAN Thomas R. Testman	Director
/s/ JON R. WAMPLER Jon R. Wampler	Director

[redacted]